BEFORE THE DELAWARE SECRETARY OF STATE

IN THE MATTER OF:	)	**Case No.: 38-03-15**
JASON BRAJER, M.D.	)	
CSR No. DR-0006589	)	

FINAL ORDER

WHEREAS, the Delaware Secretary of State ("Secretary") is in receipt of the attached Recommendation submitted by the State of Delaware Controlled Substances Advisory Committee ("Committee") regarding the controlled substance registration ("CSR") of Jason Brajer, M.D., Registration No. DR-0006589; and

WHEREAS, the Committee reviewed and deliberated on the Hearing Officer recommendation in the above matter and considered comments made by counsel for the State of Delaware; and

WHEREAS, after a hearing on the merits, the Hearing Officer found that Dr. Brajer provided care to patient Michael, who had a history of substance abuse, and that such care involved prescribing controlled substances to treat pain; and

WHEREAS, the Committee adopted the Hearing Officer's recommended conclusion of law that Dr. Brajer violated 16 *Del. C.* § 4735(b)(1) in that he failed to maintain effective controls against diversion of controlled substances; specifically Dr. Brajer failed to ensure that Michael undergo appropriate drug screening; and failed to document pill counts in Michael's chart; and

WHEREAS, the Committee adopted the Hearing Officer's recommended conclusion of law that Dr. Brajer violated 16 *Del. C.* § 4735(b)(2) in that he failed to comply with applicable federal, state or local law;" specifically, Dr. Brajer violated Board of Medical Licensure and Discipline Regulation 18.4 pertaining to pain management agreements; and

WHEREAS, the Committee adopted the Hearing Officer's recommended conclusion of law that Dr. Brajer violated 16 *Del. C.* § 4735(b)(8) in that he engaged in conduct relevant and inconsistent with the public interest; specifically, Dr. Brajer violated Board Regulation 18.4; failed to request a copy of the chart of the physician who had been treating Michael for opioid addiction; and failed to include a complete medical history and adequate and proper documentation in Michael's chart; and

WHEREAS, pursuant to 16 *Del. C.* § 4735(b), the Secretary is vested with the authority to issue discipline against a CSR; and

WHEREAS, the Secretary finds that, given the scope and nature of Dr. Brajer's violations of the Uniform Controlled Substances Act, the disciplinary sanctions recommended by the Committee are required to protect the public;

NOW THEREFORE, the Secretary of State enters the following disciplinary Order:

1. Dr. Brajer's CSR shall be suspended for a minimum of six months in that he shall be prohibited during that time period from prescribing or dispensing Schedule II controlled substances with such suspension to commence as of the date of the signing of this Final Order;
2. The suspension set forth in Paragraph 1 herein shall continue until Dr. Brajer provides the Committee with his office policies and procedures for Committee review and approval;
3. Dr. Brajer shall be required to submit a written request to lift the suspension of his CSR for review by the Committee and the Secretary;
4. The period of CSR suspension shall be followed by a minimum three-year period of probation;

5. During the three-year probationary period, Dr. Brajer shall undergo quarterly random audits of 10% of his charts with the expense of such auditing to be incurred by Dr. Brajer and with the results of such audits to be submitted to the Committee for review and approval;
6. After the three-year period of probation, Dr. Brajer may submit a written request to the Committee to have his probation lifted;
7. Any violation of the terms set forth herein, and any other violations, complaints or investigations on the same subject area at issue in this case, may be grounds for further discipline;
8. Within 30 days of the date of the Secretary of State's Final Order, Dr. Brajer shall pay a civil penalty in the amount of $3,000 in the form of a draft made payable to the "State of Delaware;"
9. Pursuant to 16 *Del. C.* § 4735(f), the Drug Enforcement Administration shall be notified of the suspension of Dr. Brajer's CSR with respect to Schedule II controlled substances and provided with a copy of the Secretary's Final Order;
10. A copy of the Secretary of State's Final Order is to be personally served upon Brajer, D.O.; and
11. The Final Order of the Secretary shall constitute a public disciplinary action reportable to public practitioner databases and will be made part of Dr. Brajer's permanent CSR file.

[signature on the next page]

IT IS SO ORDERED this 26th day of January 2017.

SECRETARY OF STATE

Jeffrey W. Bullock

APPEAL RIGHTS

29 *Del. C.* § 10142 provides:

> (a) Any party against whom a case decision has been decided may appeal such decision to the Court.
>
> (b) The appeal shall be filed within 30 days of the day the notice of the decision was mailed.
>
> (c) The appeal shall be on the record without a trial de novo. If the Court determines that the record is insufficient for its review, it shall remand the case to the agency for further proceedings on the record.
>
> (d) The court, when factual determinations are at issue, shall take due account of the experience and specialized competence of the agency and of the purposes of the basic law under which the agency has acted. The Court's review, in the absence of actual fraud, shall be limited to a determination of whether the agency's decision was supported by substantial evidence on the record before the agency.

Date Mailed: 1/27/17

cc: James E. Liguori, Esquire
Stacey X. Stewart, Deputy Attorney General
Roger A. Akin, Chief Hearing Officer

BEFORE THE DELAWARE CONTROLLED SUBSTANCE

ADVISORY COMMITTEE

IN THE MATTER OF:	)	**Case No.: 38-03-15**
JASON BRAJER, M.D.	)	
CSR No. DR-0006589	)	

RECOMMENDATION TO THE SECRETARY OF STATE

This disciplinary action arises from care rendered to a patient, Michael, by Steven Grossinger, D.O., Bruce Grossinger, D.O. and Jason Brajer, M.D., three physicians who are partners in the medical practice Grossinger Neuropain Specialists ("GNS"). Disciplinary complaints were filed by the State of Delaware against all three physicians with respect to both their medical licenses and their controlled substance registrations ("CSR"). Pursuant to 29 *Del. C.* § 8735(v)(1)d, on April 21 and April 22, 2016, a properly noticed hearing was conducted before a Hearing Officer to consider all six disciplinary actions.

At issue here is the above referenced complaint filed by the State of Delaware ("the State") against Dr. Brajer with the Controlled Substance Advisory Committee ("the Committee"). The Hearing Officer has submitted the attached recommendation in which the Hearing Officer found as a matter of fact and recommended the Committee conclude as a matter of law that the above-captioned complaint has been shown by a preponderance of the evidence presented to establish that Dr. Brajer committed violations of the Delaware Uniform Controlled Substances Act ("UCSA") and that discipline against Dr. Brajer's CSR is warranted.

Specifically, the Hearing Officer found that Michael signed two iterations of a pain management agreement. Both agreements required that Michael, a known addict,

comply with random drug screens and that he bring all unused pain medications to all office visits. Michael first presented to GNS in January 2014. While Michael was a patient of GNS and Dr. Brajer, he was not toxicologically drug screened for almost a year. When Michael failed to provide a urine sample when requested to do so in June 2014, none of the GNS physicians required that he do so until December 2014, shortly before his death from a heroin overdose. The Hearing Officer further found that Dr. Brajer did not document that any pill count was conducted during the time that Michael was receiving care at GNS. The Hearing Officer concluded that while Dr. Brajer testified that Michael did not give the outward appearance of a drug seeker, that circumstance did not permit Dr. Brajer to ignore the terms of Michael's pain management agreements for his entire period of care.

The Hearing Officer recommended that the Committee hold in abeyance any final action with respect to Dr. Brajer's CSR pending the final order of the Board of Medical Licensure and Discipline ("the Board"). The Hearing Officer further recommended that the Committee's disciplinary action track that of the Board. In addition, the Hearing Officer recommended that Dr. Brajer be required to pay a civil fine in the amount of $3,000.

The Committee is bound by the findings of fact made by the Hearing Officer. 29 *Del. C.* § 8735(v)(1)d. However, the Committee may affirm or modify the Hearing Officer's conclusions of law and recommended penalty.

The parties were given 20 days from July 26, 2016, the date of the hearing officer's recommendation, to submit written exceptions, comments and arguments concerning the conclusions of law and recommended penalty. No written exceptions,

comments or arguments were submitted by the parties. By letter dated July 26, 2016, the parties were advised that the Committee would consider the recommendation at its August 24, 2016 meeting. Deputy Attorney General Stacey Stewart appeared at the August 24, 2016 meeting and stated that the State rested on the Hearing Officer's recommendation. After discussing the recommendation, the Committee decided to table further deliberations until the next meeting, scheduled for October 26, 2016, for receipt and review of the Board's Final Order in the related case concerning Dr. Brajer's medical license.

The Committee resumed deliberations on the Hearing Officer's conclusions of law and recommendations on October 26, 2016. Deputy Attorney General Stacey Stewart addressed the Committee on behalf of the State. Ms. Stewart stated that the case concerns one patient, Michael, who was a heroin addict. On December 13, 2013, Michael treated with Dr. Lifrak, who prescribed suboxone. Michael presented to GNS on January 14, 2014. A check of the Prescription Monitoring Program database showed that Michael had been prescribed suboxone. However, no one at GNS asked Michael about suboxone or requested Dr. Lifrak's records. Michael was prescribed controlled substances for a period of a year with no urine drug screen. When Michael eventually underwent a drug screen, shortly before his death, the screen showed heroin but no controlled substances. Ms. Stewart continued that, in the Final Orders against the GNS physicians, the Board found that all three physicians were equally responsible. They missed red flags and failed to perform adequate risk assessments. While the State sought probation, fines and monitoring in the medical cases, the Board imposed reprimands, fines and additional continuing education. With respect to the complaints against the

GNS physicians' controlled substance registrations, the State requested monitoring and auditing of the practice, at their expense, fines and probation.

Pursuant to the UCSA, the Secretary of State ("the Secretary") is vested with the authority to issue discipline against a CSR. 16 *Del. C.* § 4735(b). In determining whether a CSR should be disciplined, the Secretary considers the factors set forth in 16 *Del. C.* § 4735(b). Those factors include whether a practitioner has "failed to maintain effective controls against diversion of controlled substances;" has failed to comply with applicable federal, state or local law;" or "has engaged in any conduct the Secretary finds to be relevant and inconsistent with the public interest." 16 *Del. C.* §§ 4735(b)(1), (2) and (8). The Secretary may consult with the Committee and require that the Committee review a Hearing Officer recommendation before the Secretary takes final action. 16 *Del. C.* § 4731(b).

In this case, the Hearing Officer found that while he was a patient of Dr. Brajer, Michael was not required to undergo a drug screen until just days before his death. Dr. Brajer did not document that any pill count was conducted. In short, no steps were taken to determine if Michael was actually taking the prescribed medication or whether he was using other illicit substances. The Hearing Officer recommended that the Committee find as a matter of law that Dr. Brajer's conduct constituted a failure to maintain effective controls against diversion of controlled substances in violation of 16 *Del. C.* § 4735(b)(1). The Committee accepts and adopts this recommended conclusion of law.

The hearing officer next found that Dr. Brajer violated Board Regulation 18.0. Specifically, Board Regulation 8.4 provides that patients at high risk for medication abuse or who have a history of substance abuse must sign pain management agreements outlining certain conditions. Those conditions include: drug screening when requested,

number and frequency of prescription refills, reasons for which drug therapy may be discontinued, including violation of the pain management agreement, and that patients receive prescriptions from only one prescriber and fill them at only one pharmacy, where possible. In the related case with the Board, the Hearing Officer found that Dr. Brajer violated Board Regulation 18.4. The Hearing Officer found that Board Regulation 18.4 was a regulation properly adopted within the authority of the Board and therefore had the force and effect of law. Further, the Medical Practice Act provides that it is "dishonorable or unethical conduct" under 24 *Del. C.* § 1731(b)(3) for a licensee to fail to comply with Board regulations governing the use of opioids for the treatment of pain. Therefore, Dr. Brajer's violation of Board Regulation 18.4 constituted failure to comply with applicable state law. On this basis, the Hearing Officer recommended that the Committee find as a matter of law that Dr. Brajer failed to "comply with applicable federal, state or local law" in violation of 16 *Del. C.* § 4735(b)(2). The Committee accepts and adopts this recommended conclusion of law.

Finally, the Hearing Officer found that Dr. Brajer's violation of Board Regulation 18.4 constituted violation of 16 *Del. C.* § 4735(b)(8), which provides that the Secretary may impose discipline if a registrant has "engaged in any conduct the Secretary finds to be relevant and inconsistent with the public interest." In further support of this conclusion, the Hearing Officer pointed to factual findings that Dr. Brajer should have requested a copy of the chart of the physician who had been treating Michael for opioid addiction. Dr. Brajer's charting contained an incomplete medical history and lacked adequate and proper documentation. Based on these factual findings, the Hearing Officer recommended that the Committee find as a matter of law that Dr. Brajer violated 16 *Del.*

C. §4735(b)(8) in that his conduct was inconsistent with the public interest. The Committee accepts and adopts this recommended conclusion of law.

As noted herein, the Hearing Officer recommended that the Committee track the discipline imposed by the Board against Dr. Brajer's medical license. The Board directed that Dr. Brajer's medical license would be subject to a letter of reprimand, that he be required to complete an additional nine hours of continuing education, with three each in the subject areas of drug abuse and addiction, medical record keeping and the pharmacology of pain management; and that he be assessed a civil penalty in the amount of $2,000.

The Committee declined to recommend that the Secretary impose comparable discipline against Dr. Brajer's CSR. The Committee concluded that, as a pain specialist, Dr. Brajer should have known what is required in treating an addict with controlled substances. In other words, he knew better. The Committee further noted that all three physicians were responsible for Michael's care and all three had access to Michael's records. Michael received new prescriptions without being seen by one of the GNS physicians and without being required to undergo a urine, saliva or blood drug screen. All three physicians, including Dr. Brajer, demonstrated a lackadaisical approach to Michael's care. Information about Michael's substance abuse history was available; in particular, the record in the Prescription Monitoring Program regarding the suboxone prescription, yet the GNS physicians did not detect or act on the information. The Committee likened the care provided to Michael to prescribing penicillin to a patient who is allergic to the drug and continuing to prescribe despite the patient's hives.

Given the seriousness of the violations of the UCSA, the Committee declines to adopt the Hearing Officer's recommended discipline, other than the recommended $3,000 civil penalty. The Committee, therefore, recommends that Dr. Brajer's CSR shall be suspended for a minimum of six months in that he shall be prohibited during that time period from prescribing or dispensing Schedule II controlled substances. This suspension shall continue until Dr. Brajer provides the Committee with his office policies and procedures for review and approval. Dr. Brajer shall be required to submit a written request to lift the suspension of his CSR for review by the Committee and the Secretary. The period of CSR suspension shall be followed by a three year period of probation. During the probationary period, Dr. Brajer shall undergo quarterly random audits of 10% of his charts with the expense of such auditing to be incurred by Dr. Brajer. After the three-year period of probation, Dr. Brajer may submit a written request to the Committee to have his probation lifted.

RECOMMENDATION

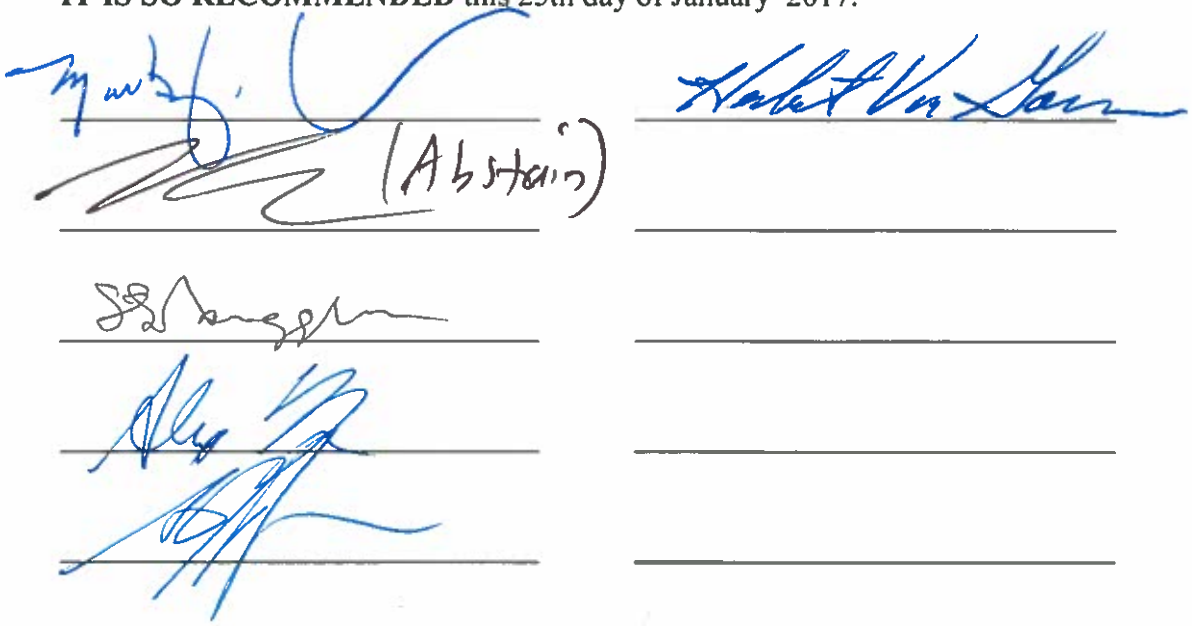
By the unanimous vote of the participating members of the Committee, the Committee recommends that the Secretary take the following disciplinary action:

1. Dr. Brajer's CSR shall be suspended for a minimum of six months in that he shall be prohibited during that time period from prescribing or dispensing Schedule II controlled substances with such suspension to commence as of the date that the Secretary of State signs the Final Order in this matter;
2. The suspension set forth in Paragraph 1 herein shall continue until Dr. Brajer provides the Committee with his office policies and procedures for Committee review and approval;

3. Dr. Brajer shall be required to submit a written request to lift the suspension of his CSR for review by the Committee and the Secretary;
4. The period of CSR suspension shall be followed by a three-year period of probation;
5. During the three-year probationary period, Dr. Brajer shall undergo quarterly random audits of 10% of his charts with the expense of such auditing to be incurred by Dr. Brajer and with the results of such audits to be submitted to the Committee for review and approval;
6. After the three-year period of probation, Dr. Brajer may submit a written request to the Committee to have his probation lifted;
7. Any violation of the terms set forth herein, and any other violations, complaints or investigations on the same subject area at issue in this case, may be grounds for further discipline;
8. Within 30 days of the date of the Secretary of State's Final Order, Dr. Brajer shall pay a civil penalty in the amount of $3,000 in the form of a draft made payable to the "State of Delaware;"
9. Pursuant to 16 *Del. C.* § 4735(f), the Drug Enforcement Administration shall be notified of the suspension of Dr. Brajer's CSR with respect to Schedule II controlled substances and provided with a copy of the Secretary's Final Order;
10. A copy of the Secretary of State's Final Order is to be personally served upon Brajer, D.O.; and
11. The Final Order of the Secretary shall constitute a public disciplinary action reportable to public practitioner databases and will be made part of Dr. Brajer's

permanent CSR file. A copy of the Hearing Officer's recommendation is attached hereto and incorporated herein.

IT IS SO RECOMMENDED this 25th day of January 2017.



cc: Jason Brajer, M.D.
James E. Liguori, Esquire
Stacey X. Stewart, Deputy Attorney General
Roger A. Akin, Chief Hearing Officer

Date mailed: 1/27/17

BEFORE THE DELAWARE SECRETARY OF STATE

In the Matter of:	)	
	)	Case No. 38-03-15
Jason Brajer, M.D.	)	
Lic. No. DR-0006589	)	

RECOMMENDATION OF CHIEF HEARING OFFICER

Nature of the Proceedings

The State of Delaware, by and through the Department of Justice, has filed professional licensure complaints against Bruce Grossinger, D.O., Steven D. Grossinger, D.O., and Jason Brajer, M.D. three physicians who are partners or associates in the medical practice Grossinger Neuropain Specialists in Wilmington DE. (On occasion those physicians will be referred to as "respondents".) The State has also filed complaints seeking discipline of the Controlled Substance Registrations (CSR) held by each of the three physicians. The factual allegations against the three respondents in the three professional licensure complaints and the three CSR complaints are similar, if not identical. Hence, by agreement of the three physicians and counsel, and in the interest of economy, a single factual hearing was convened to address those allegations. That hearing would result in recommendations to authorities on the six pending complaints.

In its complaint the State alleges that Dr. Jason Brajer is an active licensee of the Delaware Board of Medical Licensure and Discipline. He practices in Delaware at the Grossinger Neuropain Specialists practice (GNS) in Wilmington.

The State alleges that in January 2014 Patient R (who will be referred to as "Michael" throughout this recommendation) began treating with GNS with complaints of chronic pain in the neck and lower back. The State alleges that Michael had a "history of substance abuse" and was at "high risk" for medication abuse. He had been diagnosed with "opiate dependence" by a GNS practitioner.

The State further alleges that immediately before presenting at GNS in January 2014, Michael had treated with Dr. Irwin Lifrak for opioid dependence. Dr. Lifrak had discharged Michael from a Suboxone detoxification program when a urine toxicology screen was positive for illicit drugs.

The State alleges that physicians at GNS prescribed controlled substances for Michael's pain from April-December 2014. The State further alleges that Dr. Jason Brajer failed to secure Dr. Lifrak's treatment records or to speak with him regarding Michael's prior care. The State claims that Dr. Brajer failed to utilize a written treatment plan for Michael which addressed goals and objectives, plans for further diagnostic evaluations or other treatments, the necessity of further treatment modalities depending on pain etiology and the extent to which pain was associated with physical or psychosocial impairment. The State alleges that Dr. Brajer failed to appropriately adjust drug therapies, to discuss or document the discussion of risks and benefits of pain treatment with controlled substances, or to routinely order urine/serum screening or employ other controls for evaluating prescription compliance or drug abuse.

The State further alleges that Dr. Brajer failed to periodically review the course of Michael's treatment and new information about the etiology of his pain as well as his state of health, with assessment of the appropriateness of a treatment plan if progress were unsatisfactory. The State finally alleges that Dr. Brajer failed to keep accurate, complete and accessible records regarding Michael which documented or contained pain etiology, treatment objectives, discussion of risks and benefits of pain medications, informed consents, treatments, detailed information on medications prescribed, instructions to or agreements with Michael, periodic reviews with interim histories, physical exams, progress assessments and medication plans.

The State alleges that one urine drug screen was conducted on Michael during his course of treatment at GNS. That December 2014 screen tested positive for heroin but negative for prescribed medications. The State alleges that Michael died on December 12, 2014 as a result of heroin intoxication, and was discharged by GNS three days later due to the inconsistent toxicology screen result.

Based on these allegations, the State alleges in its Controlled Substance Registration (CSR) complaint that Dr. Brajer has thereby violated three provisions of the Delaware Uniform Controlled Substances Act, 16 *Del. C.* Ch. 47.

An open hearing on due notice was convened at 10 a.m. on April 21, 2016 in the offices of the Delaware Secretary of State in the State Office Building, 820 N. French St., Wilmington DE. The hearing

was continued on the next day, April 22. The State was represented by Stacey X. Stewart, Deputy Attorney General. Each of the three physician-respondents attended the entirety of the hearing. They were represented by James Liguori, Esq. All witnesses testified under oath or affirmation. A registered court reporter was present who made a stenographic record of the proceedings. This is the recommendation of the undersigned hearing officer with regard to the CSR claims made against Dr. Brajer in Case No. 38-03-15.

Summary of the Evidence

At the outset the State offered a binder of exhibits containing Tabs A-H. Mr. Liguori, on behalf of the three physicians, stated that he had in his possession Michael's complete GNS file. Mr. Liguori objected to the admission of Tab C in the State's binder. That tab contains a letter dated May 22, 2015 from Adam Balick, Esq., then counsel to the respondents, and addressed to R. Anthony Kemmerlin, Sr., an investigator employed in the Division of Professional Regulation. He argued that in the letter Mr. Balick was simply discussing certain accusations against the respondents and his statements should not be considered an admission or admissions by the three physicians. Ms. Stewart responded that the letter discussed the three pending CSR complaints against the GNS physicians. It is admissible as a response of retained counsel to those complaints. Decision was reserved on the admissibility of the Balick letter (Tab C), and the remainder of the binder was admitted as State Exhibit 1 ("SX 1").

Mr. Liguori then offered a 158-page exhibit which he represented was the entire GNS file or chart concerning Michael. Ms. Stewart objected to admission of the exhibit. She stated that she had earlier been provided with 58 pages from Michael's file, not the 158 pages now offered by the respondents. She asked Mr. Liguori when the documents in the offered exhibit had been created, and asked why a substantial number of documents had not been produced to the State prior to the hearing. The State's earlier subpoena *duces tecum* for the file had been clear as to what was requested. She objected to the admission of any document not produced by the three respondents prior to the hearing.

Mr. Liguori stated that nothing "sinister" had been intended. He added that part of the problem may have resulted in the fact that the requesting subpoena had been delivered to Dr. Bruce Grossinger's

office, and not to the GNS "main office". Ms. Stewart reiterated her objection. Mr. Liguori argued that he had not been retained by the three respondents at the time when the subpoena had been received. He added that the authors of all of the documents in the exhibit were present and subject to cross-examination by the State. He added that the chronology of care which the respondents will produce and testify to in the hearing will be accurate. Ms. Stewart responded that the subpoena for Michael's chart was served on GNS in December 2014. On January 7, 2015, Dr. Bruce Grossinger had stated that documents produced to the State represented Michael's entire file.

At this point an extended recess was taken in order to provide Ms. Stewart the opportunity to review documents in the respondents' proposed exhibit which had not been produced prior to the hearing. After the recess Ms. Stewart renewed her objection to the late production of documents. She admitted that some of the documents in the respondents' exhibit are duplicates. For instance, an undated consent form signed by Michael is included at pages 42 and 155. She asked why Bd. Reg. 18.0 (the Board's policy on the *Use of Controlled Substances for the Treatment of Pain*) was in Michael's chart. She also noted that some dates in computerized chronologies at pages 72-73 of the proposed exhibits differed, and asked if certain notes had been changed or if production had been selective.

Mr. Liguori reiterated that the authors of the documents being offered were present and could be questioned on their contents. He again asked that the entire 158-page exhibit be admitted. At this point the 158-page chart or file was not admitted, but was marked for identification as Respondents' Exhibit A ("RX A").

Ms. Stewart then waived opening statement. On behalf of the three respondents, Mr. Liguori stated that in this case all three physicians had been responsible, clinically caring and correct in their provision of medical care for Michael. There is no evidence that any of the respondents caused Michael to engage in the use of "street" drugs. The pain management provided for him was proper and in accordance with accepted protocols. There has been no departure from standard of care in this case.

Mr. Liguori continued. The three physicians acted cautiously and conservatively with respect to Michael. Care was "progressive" and Michael underwent numerous exams. The three respondents

diagnosed unrelieved pain. Their pain management of Michael was thoughtful. GNS applies a high standard of care. The State's allegations are "totally misplaced". They are "hysterical" and not supported by the evidence. Mr. Liguori concluded by stating that the hearing officer will see that the State's allegations are "off the mark". There has been no violation of Board regulations in this case.

The State first called Dr. Steven D. Grossinger, who was duly sworn. He testified that the Grossinger Neuropain Specialists (GNS) practice employs three licensed physicians, who are the respondents in these pending cases. The practice has offices in Stanton DE and in Pennsylvania. The Delaware office staff consists of two front-desk employees and 2-3 medical assistants, who prepare prescriptions, schedule patients, handle referrals and assist with patients. The focus of the GNS practice is pain management, involving diagnosis, evaluation and treatment. Both he and Dr. Bruce Grossinger are Board-certified in neurology and pain management.

Physicians in the practice consider various treatment options, including medication, physical therapy and surgery. There are no licensed nurses employed at GNS, nor Physician Assistants nor Nurse Practitioners. He testified that in this case Michael was only treated at the GNS Delaware location. The majority of care at GNS is pain management. The practice performs EMG's and nerve conduction studies. GNS does not focus on neurological problems. The practice has an interventional pain management component in the form of fluoroscopically guided injections and blocks.

Ms. Stewart asked Dr. Grossinger to identify Dr. Allen Silberman. He is a psychologist who works in the practice. He sees patients, some of whom are referred to him by GNS physicians. Dr. Grossinger characterized Dr. Silberman as "independent". He is not a GNS partner, but an associate. He occasionally evaluates the status of pain in patients, and provides psychosocial insight to GNS physicians. Dr. Silberman has hours in the Stanton office of GNS, and previously worked in Dr. Lifrak's office. Dr. Silberman saw Michael after his presentation at GNS.

GNS has Prescription Monitoring Program (PMP) access in Delaware, and made a query at the time of Michael's treatment there. Both GNS front office staff and physicians access the PMP. It is recommended that such access be made upon intake of a new patient. Typically GNS employees

document their access or queries to the PMP. Dr. Grossinger testified that he did not see such a record in Michael's chart. However, at the present time GNS employees do document PMP reports and access to that system.

Dr. Steven Grossinger testified that he performed the initial evaluation of Michael in 2014. The documents at SX 1 at Tab D at 3-9 were generated at the time of his evaluation. Dr. Grossinger identified the "psychotherapy initial evaluation" by Dr. Silberman dated January 29, 2014. SX 1 at Tab D at 11-12. On the GNS letterhead containing the Silberman evaluation, Dr. Silberman is identified as "Allen Silberman, Ed.D., LPC".

Dr. Silberman had knowledge of Michael from his work in Dr. Lifrak's practice while Michael was treating there. Dr. Silberman has the credentials to opine on whether pain management will be good for a patient. Dr. Steven Grossinger stated that he was aware of Michael's opioid addiction. He would have reviewed Dr. Silberman's initial evaluation before or at the time when he saw Michael for his second GNS visit.

Dr. Grossinger identified his initial evaluation of Michael dated January 29, 2014 and found at SX 1 at Tab D at 3-4. Dr. Grossinger was asked what was the "goal" for Michael at GNS. Dr. Steven Grossinger testified that initially Michael was "not looking to" have medications prescribed. Michael's preference is stated at the second page of Dr. Grossinger's initial evaluation. Dr. Grossinger learned that Michael was seeking treatment for pain. He was asked about the reference at the second page of his evaluation about the fact that his "PRP" (sic) noted that Michael "had gotten Suboxone last month (December 2013) though it was not refilled". In response to Ms. Stewart, Dr. Grossinger stated that he did not know why Michael was treating with Dr. Lifrak with Suboxone. He did receive information from Dr. Silberman.

The chart contains notes about Michael's physical injuries in 2008 and 2011. Dr. Grossinger agreed that there is no note in his chart about why he was receiving Suboxone treatments earlier. He now understands that Michael was being prescribed the medication to "get off" prescription medications. The PMP reflected Suboxone treatments through December 2013. Dr. Steven Grossinger then testified that

"within the last few days" he has learned that Michael was a heroin addict. He knew that Michael was being prescribed Suboxone by Dr. Lifrak. He reviewed Dr. Silberman's evaluation, which does not contain reference to illicit drug use. Dr. Grossinger knew that Dr. Silberman had previously worked with Dr. Lifrak. Dr. Grossinger did not prescribe medications for Michael. He did not contact Dr. Lifrak about Michael's earlier care of Suboxone treatments.

Dr. Grossinger knew that Michael had undergone an in-patient assessment at Rockford Mental Health Center. Dr. Grossinger gained insight into that issue through Dr. Silberman's report. SX 1 at Tab D at 11. Ms. Stewart referred Dr. Grossinger to the documents at Tab E of SX 1. They constitute the chart on Michael maintained by Dr. Lifrak and secured by the State via a subpoena. Dr. Grossinger testified that he had not seen those records previously. Ms. Stewart noted that on December 11, 2013 Michael had disclosed to Dr. Lifrak "heroin – daily" as a substance "taken within the past seven days." SX 1 at Tab E at 5. She also pointed out a January 14, 2014 note by Dr. Lifrak in his charting which indicated that Michael had produced a "dirty urine". SX 1 at Tab E at 11. Dr. Lifrak diagnosed "Opioid abuse, Anxiety, Depression" on that date and determined to halt prescription of Suboxone. *Id.*

Dr. Grossinger agreed that Dr. Lifrak's chart indicates that Dr. Lifrak found Michael non-compliant with his Suboxone treatment. He further stated that there is no reference in Michael's GNS chart that Michael was a heroin addict.

Dr. Steven Grossinger continued. In 2008 and 2011 Michael was involved in motor vehicle accidents. Two 2010 MRI's are in the GNS file. SX 1 at Tab D at 1-2. Though he did not recall when those MRI's were requested, Dr. Grossinger testified that he had access to them.

Ms. Stewart noted that Dr. Grossinger's evaluative report for Dr. Khaga Yezdani dated January 29, 2014 makes reference to care by Dr. Cary following a 2011 motor vehicle accident. Dr. Grossinger testified that a copy of Dr. Cary's chart was not requested by GNS. Nor did he know whether Michael had been compliant while in Dr. Cary's care. Dr. Grossinger did not recall seeing any prescriptions by Dr. Cary for opioids for Michael in a PMP report. He stated that, typically, the PMP gives one-year historical information.

Dr. Yezdani, Michael's primary care physician, had referred Michael to GNS. Dr. Grossinger agreed with Ms. Stewart that Dr. Yezdani's records are not part of the GNS chart on Michael. Dr. Grossinger added that Dr. Silberman brought Michael to GNS. If Dr. Yezdani had been prescribing Alprazolam and Xanax for Michael, Dr. Grossinger would consider that fact if he were planning opioids for Michael because of the potential ill effects of multiple medications.

Dr. Silberman's plan for Michael on January 29, 2014 is found at SX 1 at Tab D at 12. It included psychotherapy and encouraging compliance with his drug treatment program with help for chronic pain. Dr. Grossinger agreed that in January 2014 Michael had not been compliant with Dr. Lifrak's plan. Dr. Grossinger does not recall asking Michael why he was no longer being prescribed Suboxone. Dr. Grossinger recalls that Michael said he had been prescribed the drug but had stopped because he did not want further medications. Neither Michael nor Dr. Silberman disclosed Michael's heroin addiction. Michael's initial course at GNS did not include controlled substances.

Ms. Stewart asked Dr. Grossinger if he were aware of why Michael's Suboxone treatments had ceased. He stated that initially he did not have a report. A report was available to him at the time of Michael's second visit. Dr. Grossinger believed that Michael was treating for pain with Dr. Lifrak. But Dr. Grossinger had no specifics regarding heroin use by Michael which would cause him to consider that the Suboxone was prescribed for that purpose. At the present time if a new patient presented himself at GNS and had been treating previously with Suboxone, Dr. Grossinger would try to get insight into the prior care. He reiterated that neither Michael nor Dr. Silberman had mentioned his heroin use. Dr. Grossinger does not recall asking Michael if he used illegal drugs. Today he does ask such questions.

A questionnaire for patients at GNS is found at SX 1 at Tab D at 13-15. Dr. Grossinger admitted that the form does not inquire into the use of illegal drugs. The same form is used at GNS today. The GNS Pain Management Agreement (SX 1 at Tab D at 16) does refer to illicit drugs. It informs patients that toxicology screening will be done to detect illegal drug use. Dr. Grossinger admitted that the form does not ask the patient to disclose whether he is using such drugs. The pain management agreement used at GNS was drafted or approved by "pain societies".

Michael was not toxicologically screened at the time of his first visit to GNS. Dr. Silberman wrote his evaluation and plan for Michael knowing that Dr. Lifrak had discharged him. Ms. Stewart asked Dr. Grossinger why Michael did not seek medications for pain. Dr. Grossinger did not recall. He believes Michael wanted drug-free treatment. He then admitted he had no specific recollection. Ms. Stewart asked why Michael was asked to sign a pain management agreement if he were not to be prescribed controlled medications. Dr. Grossinger stated that patients need to be aware of office policies. The form was not signed because he was contemplating prescribing controlled substances in the future.

When he signed the agreement, Michael did not identify his regular pharmacy. However, the GNS EMR system and the PMP identified his pharmacy. He added that at the present time patients do identify pharmacies. When Dr. Bruce Grossinger shook his head in disagreement with Dr. Steven Grossinger, he was instructed not to prompt or aid the witness. Dr. Steven Grossinger then agreed with Ms. Stewart that the GNS pain management agreement does not discuss or describe the risks and benefits of use of controlled substances in the management of pain.

Dr. Steven Grossinger testified that in January 2014 he performed a nerve conduction study on Michael. In February 2014 he evaluated Michael with the assistance of an EMG of the back and legs. He then asked Dr. Brajer to perform x-ray guided epidural injections in two separate procedures. Injections were performed in late February. No controlled substances were prescribed that month.

In March 2014 Tramadol was prescribed. Though the medication was not a controlled substance in early 2014, it became so later in that year. In April 2014 Dr. Brajer began to prescribe Hydrocodone on a 30-day basis. The medication is a controlled opioid. Dr. Grossinger stated that it is important to observe clinical appearances and other details when prescribing controlled substances for a heroin addict. Certain clinical signs and behaviors should be observed to identify addiction. To Dr. Grossinger's knowledge, at this time in 2014 Michael was not enrolled in a drug treatment program.

He agreed that toxicology screening can be used to check for the use of illicit drugs. He agreed that that was not done with Michael until December 2014. Other checks include a determination of whether a patient is asking for increased numbers or strengths of doses. Asking for increases or asking

for refills early can be evidence of "craving". Dr. Grossinger knew that Michael was "opioid dependent" as noted in Dr. Silberman's evaluation. Dependency differs from addiction. Dr. Grossinger was unaware of prior addiction in Michael. Dr. Silberman had indicated that Michael was opioid "dependent". Dr. Grossinger then admitted that Dr. Silberman's evaluation notes "opiate addiction" for five years in his evaluation when he described the course of Michael's care. SX 1 at Tab D at 11. Nonetheless, in early 2014 Michael showed compliant behaviors not indicative of addiction.

Dr. Grossinger testified that he had no way of knowing if Michael was consuming a 30-day script in one day, or whether he was using illicit drugs. In his opinion Michael was behaving as he did in order to get better, and not to get drugs. When Michael sustained a new physical injury, he was first tried on non-narcotic medications. Dr. Grossinger admitted that GNS did not engage in pill counts with Michael.

Dr. Steven Grossinger is familiar with Bd. Reg. 18.0. He stated that Bd. Reg. 18.4 (the provision in the regulation requiring pain management agreements) addresses "high risk" patients. Dr. Grossinger agreed that Dr. Silberman stated that Michael was "dependent" on medications. He reiterated that Michael did not show addictive behaviors. He wanted pain treatment without medications. He did not behave as would a patient who had presented in order to get medications. He admitted that Michael was a high risk patient for abuse when he first presented at GNS.

Dr. Grossinger admitted that Bd. Reg. 18 discusses tox screening, pill counts and limiting purchases to a single pharmacy. Dr. Grossinger may have recalled that a tox screen for Michael was ordered in May 2014. Ms. Stewart drew his attention to SX 1 at Tab D at 49. That is a report of cervical facet medial branch blocks performed by Dr. Brajer on May 28, 2014. Dr. Grossinger agreed that no screen was ordered in that report. Dr. Grossinger responded by stating that GNS computer records show that a screen was ordered in May 2014, but that Michael canceled his appointment at GNS that month. Dr. Grossinger agreed that no toxicology screening of Michael was ordered during the period July-November 2014. Dr. Grossinger stated that during that period Michael was compliant. He did not asks for refills early. Some were issued late. That is not indicative of addictive behavior.

Since providing care for Michael, GNS has instituted certain changes. The PMP is checked more frequently. All patients are screened "out of an abundance of caution".

The questioning of Dr. Steven Grossinger then returned to the timeline of Michael's care at GNS. In June 2014 Dr. Grossinger prescribed morphine and Hydrocodone for Michael. He had allowed the full 30 days to expire after Michael's May visit to GNS. Dr. Grossinger stated that he "had access" to certain records prior to Michael's June 2014 visit. His review indicated that Michael had been compliant in GNS care. The records he reviewed indicated that Michael had not requested controlled substances, and that GNS prescriptions had started medications at low doses. It was medically appropriate to prescribe as he did for Michael in June.

Ms. Stewart asked Dr. Grossinger if he were concerned at the time with prescribing opiates for Michael. Dr. Grossinger stated that he is "always concerned", but that he had reassurances that Michael had been compliant. Dr. Grossinger does not recall discussing "risks and benefits" of using opioids with Michael. Michael did sign the GNS consent form. The two discussed other pain treatment modalities. Dr. Grossinger knew that Dr. Brajer was following Michael closely. Dr. Brajer discusses risks and benefits with patients. Dr. Grossinger agreed that Michael's chart does not record such discussions. Dr. Grossinger agreed that a note in the chart in April 2014 contains a handwritten reference to Hydrocodone. Nonetheless, at the time Dr. Brajer was considering "all options". Prior to June 2014, non-controlled substances had been prescribed for Michael, and had been adjusted thereafter.

In July 2014 Dr. Brajer had increased Michael's morphine dosing, as reflected in the Brajer note of July 30. SX 1 at Tab D at 66. Ms. Stewart asked why dosing of MS Contin was increased by Dr. Brajer on that date from 15mg to 30mg. Dr. Grossinger stated that this was done to maintain Michael at the lowest dose possible. Michael had been receiving consistent care since his presentation in January 2014, and no one had noted problems. Therefore, the same course of treatment was maintained for him. They had worked to stay with the 15mg dosing for Michael. Dr. Grossinger agreed that a different script by Dr. Brajer was not documented.

From September-December 2014 there are no treatment records for Michael in the GNS chart. Michael did not appear for an appointment on October 27, 2014. He had called in sick on the date of one scheduled visit. On December 8, 2014 Michael was informed that no further prescriptions would be written for him without a new office visit. Dr. Grossinger testified that Michael appeared to remain compliant. He had not requested medication changes or early scripts, and had signed a consent when he picked up his scripts. According to Dr. Steven Grossinger, there were no signs of addictive behaviors.

Ms. Stewart asked Dr. Grossinger if he had reason to believe that Michael was a "savvy" drug user. Dr. Grossinger responded that if Michael were so, his behaviors were not consistent with such a person. Ms. Stewart asked if "high risk" patients are aware that they should not claim they have run out of medications early. An objection on the basis that the question called for Dr. Grossinger to speculate was overruled. Dr. Grossinger stated that there were no signs that Michael was diverting drugs. He was pleasant and well maintained and showed up on schedule. No "red flags" had appeared. There were no indications that tox screening should be ordered, or that his care should be altered.

A reference in a screen shot or "note scan" of electronic GNS records states that in July 2014 Michael was informed that he "must keep appointments". SX 1 at Tab D at 73. Dr. Grossinger stated that such an instruction to a patient is not a red flag. Ms. Stewart asked why only the visits of July-December 2014 are referenced on that page. Mr. Liguori directed Ms. Stewart's attention to RX A at 72-73, which scans all notes from January-December 2014. Dr. Grossinger stated that staff inputs the data in those "note scans". Dr. Grossinger was not aware of the existence of additional notes on Michael for the period prior to July 2014. Notes regarding certain medication adjustments for Michael are found at RX A at 50. Dr. Grossinger testified that those notes were located in "another system" to which the practice had switched. He stated that the switch did not impact "old notes".

In October 2014 Dr. Grossinger wrote scripts for Michael without the benefit of an office visit. On December 8, 2014 Dr. Steven Grossinger ordered toxicology screening for Michael. When completed, that was the first time he had been screened while in GNS care. The screen was abnormal in that it produced a positive result for heroin metabolite. When that result was received, Michael was

discharged from the practice. Dr. Grossinger later learned that Michael had died either on December 14 or 15, 2014. (The date of death is officially noted as December 12, 2014. SX 1 at Tab F.) Dr. Grossinger was not aware of the death at the time when Michael was discharged. He is aware that the cause of Michael's death was heroin intoxication.

On July 11, 2014 Dr. Grossinger authored a lengthy report to Joseph W. Benson, Esq. SX 1 at Tab D at 60-64. Dr. Grossinger testified that his report did not recommend more medications. He provided future treatment recommendations. Dr. Grossinger conceded that he continued to prescribe for Michael after writing the report. It was an accurate report with regard to injuries sustained or aggravated in a 2010 motor vehicle accident. Dr. Grossinger had been requested to opine with regard to the injuries and related treatments. Dr. Grossinger agreed that the July 2014 report to counsel does not mention GNS prescribing of controlled substances for Michael. It does mention previous subscribing of such medications by Dr. Ufberg and Dr. Cary.

Dr. Steven Grossinger admitted that GNS and its physicians were represented earlier in this case by Adam Balick, Esq. On their behalf, Mr. Balick had filed a response to the CSR complaints filed by the State against the three respondents. Dr. Grossinger is aware that in a letter (SX 1 at Tab C) Mr. Balick had agreed that GNS had been non-compliant with Bd. Reg. 18 in this case in some respects. Dr. Grossinger also agreed that Mr. Balick had copied that letter to GNS, and that it had not been amended after it was mailed to a Division investigator. Dr. Grossinger further agreed that "substantial" changes had been made in GNS practices and procedures after this case.

At this point Ms. Stewart had concluded her direct examination of Dr. Steven Grossinger. Without objection by the State, the respondents were then permitted to call a witness "out of order" in the case. They called Peter S. Staats, M.D. as an expert witness.

At the outset Dr. Staats testified regarding his professional credentials. He received undergraduate degrees from the University of California at Santa Barbara and his medical degree from the University of Michigan in 1989. He interned at the University of Hawaii and served a three-year

residency at Johns Hopkins in the Department of Anesthesiology and Critical Care Medicine. He then served a one-year fellowship in Pain Medicine at Johns Hopkins.

From 2004-present Dr. Staats has practiced in New Jersey. He remains an adjunct on the Johns Hopkins faculty in the Department of Anesthesiology and Critical Care Medicine and the Department of Oncology. He is Board-certified in Anesthesiology and Critical Care as well as in Interventional Pain Management. He is President of the New Jersey Society of Interventional Pain. He listed a number of awards which he has received during his medical career.

A copy of Dr. Staats' 38-page curriculum vitae was admitted as Respondents Exhibit 1 ("RX 1"). Though I will comment on Dr. Staats' opinions and their bases later in this recommendation, at this point I simply note that his credentials to testify and to provide opinions in a case such as this one are impressive and his expertise is broad and relevant.

In response to Mr. Liguori, Dr. Staats testified that he had reviewed Michael's entire GNS chart in preparation for his opinions and his testimony here. Dr. Staats identified his report in this matter to Mr. Liguori dated April 20, 2016. That report was admitted as RX 2.

Dr. Staats was first questioned about the historical underpinnings of the "Model Policy for the Use of Controlled Substances for the Treatment of Pain" adopted by the Federation of State Medical Boards (FSMB). In the 1980's there was a prevalent opinion that those persons not suffering from cancer-related pain should not be prescribed opioids. Subsequently, professional thinking on that subject changed. In the mid-2010's the FSMB therefore determined that physicians treating patients afflicted with chronic non-cancer pain should not fear prescribing such medications. Physicians should use their best judgment in treating patients. The FSMB realized that the Hippocratic Oath requires that physicians help their patients. The "Model Policy" therefore states that such prescribing can be proper for pain patients.

With regard to Michael, there was a legitimate purpose for GNS's prescribing of controlled substances. They were trying to control his pain, and therefore they broadly followed Bd. Reg. 18. He added that the drugs prescribed in this case for Michael were appropriate for his diagnoses.

Returning to the historical record, Dr. Staats testified that from 2010-2014 opioids became more accepted in the treatment of chronic pain. In 2014 under 100mg per day in morphine equivalent became "the number". At the present time the Centers for Disease Control has announced that 40mg is the appropriate maximum dosage for primary care physicians, though not for pain specialists. In 2015-2016 the environment changed and caution is now urged because of the risks presented by controlled substances.

With regard to urine toxicology screenings, Bd. Reg. 18.4 states that physicians should employ them in their best judgment. However, the policy does not specify what that means, i.e. weekly, monthly, quarterly, etc. Physicians are now moving toward a more "judicious" use of screening. When Michael was treated at GNS in 2014, there was no specific stated standard for screening. Some physicians advocate that all pain patients should be screened. However, that is not the "standard". Dr. Staats stated that now perhaps 1 million individuals suffer significant pain.

Dr. Staats testified that even if a patient has an addiction disorder, a physician may still prescribe opioids for him. He conceded that some argue that an addicted person should not be prescribed opioids. A national expert now says that a physician should "co-manage" the addiction and the pain. There is no "red line" which delineates who should be prescribed opiates. In Michael's case, pain medications were prescribed by GNS physicians judiciously, in Dr. Staats' opinion. He agreed with Dr. Steven Grossinger that no red flags in the form of missed appointments, early requests for refills, and the like were evident in Michael's chart. However, in hindsight, Dr. Staats now sees Michael's addictive history. He reiterated that even with an addicted patient, prescribing pain medications can constitute responsible medical practice.

In his role as an officer of the American Society of Interventional Pain Physicians, Dr. Staats has written and lectured on controlled substance management. He has met with New Jersey Gov. Christie to discuss the subject, and has discussed it with other physicians. He noted that some physicians associated with "pill mills" are not engaged in the legitimate practice of medicine.

In this case Dr. Staats saw that GNS physicians were trying to evaluate Michael, review diagnostic work, consider differing modalities and create and adjust a treatment plan. Michael's death was "extremely unusual" in the GNS practice. The respondents were "trying to do the right thing". Dr. Staats stated that Michael's death was "not directly causally related" to GNS care. He added that Methadone maintenance programs can reduce the incidence of individuals returning to street drugs.

Mr. Liguori asked questions of Dr. Staats concerning the State's professional licensure complaints in this case. The six complaints are found at SX 1 at Tab A. With regard to the allegations in para. 6 of the licensure complaints, Dr. Staats observed that being a good physician now is "tough". In this case Dr. Staats saw no "cloning" in Michael's chart, i.e. simply restating a prior note. With regard to the allegation that the respondents failed to request Dr. Lifrak's chart or to speak with him, Dr. Staats stated that Dr. Silberman did convey certain information to the respondents in his initial evaluation.

With regard to the claim that the GNS physicians did not develop a written treatment plan for Michael, Dr. Staats stated that in this case he saw a "thought process" in Michael's prescriptions. The physicians identified problems and took a conservative approach regarding other therapies. Tramadol, with a binding effect of 1/600 of morphine, was tried. Tramadol is less addicting. Michael was then placed on low doses of opioids, which were then increased or changed.

The State alleges that the GNS physicians did not discuss or document discussions with Michael about risks and benefits associated with the use of controlled substances. Dr. Staats replied that Michael "knew these things". With regard to the State's claim that routine tox screening was not ordered by the respondents, Dr. Staats reiterated that guidelines do not require any particular regularity in screening. There is no consensus presently on that subject. Dr. Staats believes that the GNS physicians complied with Bd. Reg. 18. They had "periodically" ordered screening.

With regard to the claim that the respondents failed to periodically review the course of Michael's treatment and new information about the etiology of his pain and state of health to assess the appropriateness of the current plan, Dr. Staats stated that the GNS physicians did order or perform

studies. Some things were tried. Records were not "cloned". In this case Dr. Staats thought that Michael's plan was gradual, step-wise.

The State alleges that the respondents failed to keep complete patient records. Dr. Staats responded that physicians can, of course, always have more records. However, not all information received gets into patient charts. Dr. Staats opined that a "good job was done" here. Michael's chart is well-documented. GNS is not a "pill mill". The GNS physicians were judicious and tried to do their best. In Dr. Staats opinion, and based on a reasonable degree of medical probability, care offered by GNS to Michael was good. There were different addiction and pain issues. The death of Michael was not directly related to GNS physicians prescribing opioids for him. The heroin came from a different source.

Ms. Stewart then cross-examined Dr. Staats. He reviewed his Board certifications. He also has a private pain practice. Dr. Staats did not speak with Dr. Silberman regarding this matter. He knew that Dr. Silberman had worked with Dr. Lifrak. He does not know if Dr. Silberman discussed Michael with Dr. Lifrak. Dr. Staats could not disagree with Ms. Stewart's representation that such a discussion did not take place.

In this case Dr. Staats reviewed Michael's GNS chart, Bd. Reg. 18, some FSMB materials and the State's complaint. He also viewed the GNS website. He did not review Dr. Lifrak's chart on Michael. Dr. Staats was aware of Michael's opioid addiction. He does not know that Michael was treated by Dr. Lifrak with Suboxone for heroin addiction. That does not change his opinion in this case.

It was "judicious" not to start Michael on opioids at the outset. Prescribing opioids to addicted persons can present risks. If Dr. Staats saw a patient today with a heroin "history", he would order toxicology screening monthly if he were to prescribe opioids. Ms. Stewart read a quote from a Board order regarding failure of a pain management physician to secure prior records. Dr. Staats stated that the passage was "too simplistic" for this case. He agreed it is "much better" to have complete records. If Michael had a heroin disorder, a physician "had to" secure records. He added that mental health and addiction records on patients are hard to secure or transfer.

Dr. Staats testified that addicted patients rarely admit that fact. Nor do they admit that they were discharged by another physician. Before accepting a new patient, Dr. Staats would want to have medical records if he were to take over a case. Illegal drug use could be learned from a prior physician's records. That would have been "additional information".

Ms. Stewart provided Dr. Staats with Dr. Lifrak's chart (SX 1 at Tab E). She cited to a December 11, 2013 record in which Michael had disclosed "heroin daily" six weeks before presenting at GNS. Dr. Staats conceded that a review of those records would have revealed heroin use. She asked Dr. Staats if he had learned of prior Suboxone treatment and that such treatment had ended, would he have requested Dr. Lifrak's chart. He stated that he would have requested the chart. Nor is he certain that he would have prescribed opioids for Michael. That decision would depend on "available information". A physician has to "make a judgment". When asked whether it is reasonable to prescribe opioids for a non-compliant heroin addict, Dr. Staats stated the the GNS physicians would have known of the heroin addiction had they asked for Dr. Lifrak's records.

Dr. Staats stated that Dr. Grossinger said that he speaks with all patients regarding opioids. He is aware that Dr. Brajer prescribed them for Michael. Dr. Staats agreed that there is no documentation of the discussion of risks and benefits of opioids in Michael's GNS chart. He is aware that Bd. Reg. 18 requires documentation of such discussions. Dr. Staats then stated that he believed that Bd. Reg. 18 did not become law in Delaware until 2015. He agreed that if Bd. Reg. took effect in 2012, the lack of documentation of a risks/benefits discussion is a violation.

Dr. Staats testified that in this case he looked at the "big picture". The GNS physicians are good doctors who were trying to care for patients. He added that "pill mills" (not GNS) are a "plague on society". He looked at this case from a "medical quality of care" standpoint, a "high level" view. He admitted that pain practices other than "pill mills" are capable of violating the law.

Dr. Staats then offered a traffic analogy. He stated that driving at 200 m.p.h. in a 50 m.p.h. zone is different from driving 51 m.p.h. in the same zone. Though both acts are violations of the law, they are very different. Dr. Staats admitted that a violation of Bd. Reg. 18 need not be "gross". He also agreed

that the fully informed consent of Michael was not timely secured in this case. With regard to treatment plans, Bd. Reg. 18, in Dr. Staats' view, requires a "broad plan". That was done here. In other words, controlled substance dosing was started at low levels, and then adjusted upward. Michael's opioid scripts in this case were for chronic pain. That is "self-evident" here.

Dr. Staats then testified that asking a patient if he is using illegal drugs should be "standard" before prescribing opioids. He stated that that is the standard today. He noted that patients who are seeking controlled substances illicitly "never tell me the truth". He usually finds out about prior Suboxone treatment by checking a prescription monitoring program. A PMP can be useful in determining if a patient is being truthful. He uses the PMP before accepting a new patient on referral. Though a PMP query cannot disclose use of illicit drugs, it can be used to determine if a patient is doctor-shopping. It is "one tool" to get at the truth.

Dr. Staats uses toxicology screening and the records of other prescribers to determine the truth. Pill counts can be used in some cases, but patients can lie about the counts. Further, a pill count for "little old ladies" at mid-month can be an imposition. Counts are better for patients who are being prescribed high dosages of opioids.

The GNS chart shows that tox screening for Michael was ordered in June and July 2014. The GNS chart does not contain chart entries that he had missed those screens. When Michael had missed appointments, Dr. Staats probably would have ordered a follow-up screen.

Dr. Staats stated that there are significantly increased risks when a physician is co-managing pain and addiction. In addition, Michael was being prescribed medication for anxiety. Ms. Stewart indicated that a PMP report at SX 1 at Tab D at 74 shows that Michael was being prescribed medications for anxiety. Dr. Staats agreed that the GNS chart does not reflect coordination between GNS and other prescribers. Dr. Staats testified that a pain physician is "not typically" required to coordinate with a psychiatrist. However, he does prefer to know about such treatment. The main risk is overdosing when a patient is being concurrently prescribed opioids and anxiety medications. Among other risks, there is a risk of depressing the respiratory system when multiple medications are combined.

Dr. Staats then added that Michael died from another cause, i.e. heroin overdose. There is thus no cause and effect between his death and multiple controlled substances. Dr. Staats stated that if toxicology screening of Michael in June 2014 had disclosed a positive heroin result, he would have referred Michael for drug treatment. He added he did not think that addiction plus opioids plus anxiety medications would amplify the need for screening. In other words, if a psychiatrist had added an anxiety drug, that does not heighten the need for a screen. In this case he tried to put himself in the shoes of the GNS physicians. In the past Dr. Staats has prescribed opioids for drug addicts. He offered the case in which he prescribed opioids for an addicted motor vehicle accident victim who had sustained massive facial injuries.

Dr. Staats opined that opioids were the "right answer" for Michael. He observed that medical boards never state that opioids should not be prescribed for addicts. Physicians should use "judicious care". Mr. Liguori had informed Dr. Staats prior to the hearing that no deaths had resulted from care by GNS. Dr. Staats agreed that GNS consent forms could have been "more thorough". The GNS form did not discuss addiction and risks. Nor do Dr. Brajer's notes indicate the discussion of opioids with Michael in light of his history.

Mr. Liguori then questioned Dr. Staats further. In a future book Dr. Staats intends to discuss "balanced" approaches to pain patients. He added that Ms. Stewart's questions regarding addicted pain patients are valid, though her questions do not change his opinions. Care must be balanced, and opioids are one of many strategies with patients. He added that he hopes that "pill mills" will soon be history. He does not agree with all pronouncements from the CDC. Intervention strategies should be attempted. He added that Michael's chart was "balanced", though it could have been "better". He observed that Michael did not die due to poor documentation of his medical care. Dr. Staats "feels for him". He had two problems. He noted that GNS did not begin prescribing opioids for Michael for four months.

At the beginning of the second day of the hearing, Mr. Liguori began his questioning of Dr. Steven Grossinger with a further review of the chronology of Michael's care at GNS. Dr. Grossinger saw Michael on January 29, 2014 after Michael had been evaluated by Dr. Silberman. Dr. Silberman had indicated that Michael was interested in management of his pain. Dr. Grossinger performed an EMG and

nerve conduction study of the extremities. He found multiple nerve root injuries. Michael provided him with certain history, including neck and shoulder pain. He had sustained shoulder and arm injuries in a 2008 motor vehicle accident. Those injuries were aggravated in another accident in 2011.

Michael had treated with Dr. Cary, and then had no pain treatments for a year. Dr. Grossinger performed an independent medical evaluation and had reviewed Dr. Cary's chart. Dr. Grossinger performed a physical exam and diagnosed abnormalities, muscle spasm, and other issues. He reviewed an MRI and, after a further test, he diagnosed bilateral nerve injuries. They discussed treatment, and Michael stated that he did not want medications. A PMP report indicated that he had been receiving weekly Suboxone treatments. SX 1 at Tab H. However, the Suboxone treatments had ceased for six weeks. Micheal stated that he did not like the medication. An intake form indicated that he had been prescribed Oxycodone and morphine.

On March 19, 2014 GNS prescribed for Michael. Dr. Grossinger testified that SNS "never" prescribes Oxycodone 30mg or morphine 30mg. Those are "high" doses. Michael was prescribed 1/6 of the Oxycodone dose equivalent and ¼ of the morphine dosing. More tests were planned, and Michael was to return for an epidural. The first iteration of his treatment plan did not include medications.

On February 26, 2014 Dr. Grossinger had seen a "Suboxone report". Michael had been treated for two years, had undergone a Rockford admission, and had been prescribed Suboxone by Dr. Lifrak. Michael's course of treatment was "clear" to Dr. Grossinger, who did not want to treat Michael with medications in January-February 2014.

Dr. Grossinger received MRI results and Dr. Silberman's report, in which opioids were discussed. Dr. Grossinger recalls that the Silberman report indicated that Michael was opioid "dependent", and not addicted. On February 26, 2014 a second EMG was conducted. A needle was used to electronically stimulate nerves. Responses were electronically recorded. Needles were also applied to the arm, shoulder and neck. Later, testing was done on the back, foot and leg. Dr. Grossinger discussed the case with Dr. Brajer. GNS proceeded without medications on February 26. Michael then returned to GNS for an office visit with Dr. Brajer. During the presentation of respondents' testimonies, a media technician

who was in attendance at the hearing displayed certain documents or summaries on a large screen in the hearing room. One of those "screens" was later admitted into evidence.

Dr. Steven Grossinger did not see Michael on October 10, 2014. He did write a refill for Michael. He deemed Michael "compliant" since his presentation in January. Medication dosing had been adjusted at certain points during his care by GNS. In October Dr. Grossinger reviewed Michael's chart and conferred with staff in making the determination that Michael had been compliant. He then decided to write a refill script for Michael. This provided continuity of care. Dr. Grossinger noted that Michael had not asked that the refill be increased. Nor had he asked that scripts be refilled early.

On December 8, 2014 Michael returned to GNS. He complained of headache, neck and low back pain. He had been exercising at home, and was out of work. Dr. Grossinger examined him. He diagnosed restrictions on mobility and range of motion. He gave Michael cortisone injections in the lumbar spine, and order a low back MRI. A lumbar epidural was scheduled for his next visit.

Dr. Grossinger reviewed the results of Michael's toxicology screen. Michael had not asked that his medications be increased or replaced. "Constant care" was appropriate for him. Returning to the speeding analogy he made earlier in his testimony, Dr. Grossinger opined that dosing of 30mg Oxycodone and 60mg morphine was tantamount to driving at 200 m.ph. in a 50 m.p.h. zone. So GNS prescribed for him at the "50 m.p.h." level. Dr. Grossinger had prescribed 15mg morphine and 5mg Hydrocodone, twice daily for each. Dr. Steven Grossinger made the decision to discharge Michael by letter to him on December 12 or 13, 2014. GNS later received the report that Michael had died.

Ms. Stewart examined Dr.Steven Grossinger further. Dr. Grossinger was unaware of the care provided for Michael by Dr. Cary. Dr. Cary's chart was not requested by GNS. Michael's last Suboxone script had been written in early January 2014. Dr. Grossinger therefore corrected his earlier testimony and stated that Michael had been off Suboxone for three weeks, not six. He defined a "dirty" toxicology screen result as one which is inconsistent with prescribed medications or which may disclose the use of illicit drugs. Dr. Lifrak had noted a "dirty" screen for Michael in early January 2014.

Dr. Steven Grossinger testified that he has a better recollection now about his conversations with Michael. He does not have an "independent, specific" recollection of the discussions. Ms. Stewart asked Dr. Steven Grossinger whether it was true that Michael had expressed a dislike for Suboxone. Dr. Grossinger stated that he did not believe that was untrue. Dr. Lifrak's records say that he had discharged Michael, who had misled him. Dr. Grossinger added that had Michael been truthful with him, his course of treatment at GNS would have differed.

The State next called Dr. Jason Brajer. He performed a cervical epidural steroid injection on Michael on February 26, 2014. He stated that an "Injection Intake Information" form at SX 1 at Tab D at 27 was filled out by a GNS medical assistant. He reviewed it and checked it for accuracy. A reference to "other medications" on the form bears the note "see list". Dr. Brajer testified that the assistants now list all medications on the form. He acknowledged there was no "list" in Michael's chart. He added that had there been such a list, it would not have been shredded. It is his practice to direct that such documents be shredded, along with PMP reports. In this case no such list for Michael was shredded because, at the time, GNS was not prescribing for him.

Dr. Brajer stated that in February 2014 he did not review a PMP report on Michael. He was not aware that Michael had been prescribed Suboxone through early January 2014. Nor had he reviewed Dr. Silberman's report. That report was not provided to him.

In March 2014 Dr. Brajer saw Michael again for an injection. Michael stated that he had "pulled" his back. Dr. Brajer prescribed Meloxicam (not a controlled substance) and Ibuprofen or Motrin 15mg, ½ tab per day as well as Tramadol twice daily prn. Dr. Brajer did not review Dr. Steven Grossinger's charting on Michael. His records were kept in the GNS Pennsylvania office. It was the practice at the time at GNS to retain records in the Delaware GNS office only for the most recent encounter (in this case, that of February 26, 2014). Dr. Brajer described a process by which he often carried records back and forth from one GNS office to another.

Dr. Brajer wanted an MRI and/or EMG to determine whether injection therapy would be appropriate for Michael. Dr. Brajer treated Michael without reviewing initial reports by Dr. Steven

Grossinger or Dr. Silberman. In response to the hearing officer, Dr. Brajer stated that if he did not have access to an EMG or other reports, he could ask an assistant to secure Dr. Steven Grossinger's report for review. It is important to "justify" an injection. Dr. Brajer started Michael on controlled substances. He had given Michael the "talk" previously. Though that "talk" is not recorded in Michael's chart, that was his "routine". When he began treating Michael, he was not aware of opioid dependency in Michael. He did not order toxicology screening of Michael before he began prescribing for him. Dr. Brajer stated that he was unaware of Michael's previous treatment for heroin use. He did not know that Dr. Lifrak was treating him for that use.

Ms. Stewart drew Dr. Brajer's attention to Dr. Lifrak's chart on Michael. SX 1 at Tab E. Dr. Brajer briefly reviewed the contents of that chart. He acknowledged the reference in which Michael admitted to "daily" heroin use. A note by Dr. Lifrak at SX 1 at Tab E at 6 states that "(p)atient usually uses over a Bundle of Heroin per day and has been doing so for 6 years with some periods of sobriety." Dr. Brajer also acknowledged the reference in which Dr. Lifrak notes that he had been prescribing Suboxone for Michael. Dr. Brajer testified that he did not know Michael was being treated for heroin use. He stated that the Suboxone could have been prescribed for pain. Dr. Brajer agreed that the Lifrak note on Michael made no reference to pain. He acknowledged the reference in the same Lifrak note to "treatment with Suboxone detoxification". SX 1 at Tab E at 7. Dr. Brajer testified that he agrees the Suboxone was being prescribed for heroin addiction.

Dr. Brajer was referred to his "injection intake information" form at SX 1 at Tab D at 40. On April 9, 2014 he determined to "add HC 5/325". He did so because the earlier prescribed Tramadol had been ineffective. He therefore offered to increase the dosing of Michael's pain medications. He discussed prescribing narcotic drugs with Michael. He reiterated that "every patient" gets the "slippery slope" talk and proper control of pain episodes. "Logic" told him that the Tramadol had been ineffective. Any "responsible " physician would have made the decision that he did.

Dr. Brajer agreed that his charting of Michael does not include documentation of his discussions of "risks and benefits" of opioid pain medications with Michael. He did not ask Michael if he were using

illicit drugs. "Patients lie" about those subjects. He added that "everyone" wants the use of opioids to be short term. "Edicts" from professional associations and others require that "short term" prescribing of such medications be discussed with patients.

A lengthy, typed report captioned "Cervical Selective Nerve Root Blocks" dated April 30, 2014 and found at SX 1 at Tab D at 41-43 does not contain a "medication plan". He admitted that the report does not list non-controlled substances then being prescribed for Michael. The April 9, 2014 "injection intake information" reference to "see notes" for "other medications" was made by another person. Such "notes" no longer exist because they have been shredded. In April 2014 Dr. Brajer did not prescribe toxicology screening for Michael. Nor did he order a PMP report.

Dr. Brajer continued. He considered Michael a "high risk" patient for drug abuse. He did not consider him "high risk" at the time of his care by GNS. He agreed that had he read Dr. Silberman's report at that time, he would have learned of that fact.

He identified SX 1 at Tab D at 28 as Michael's signed consent to injections. Patients must sign the form for each scheduled injection. Patients are also required to sign pain management agreements which inform them of their responsibilities. He agreed that the GNS pain management agreement does not inform patients of the risks and benefits of pain medications. However, patients "get a talk" whenever dosing is changed. He agreed that Michael's chart does not document such "talks".

Dr. Brajer testified that on May 28, 2014 late day morphine was added to Michael's medication protocol, while morning dosing of Hydrocodone was maintained. A patient receives a similar effect from both medications. When Michael stated that he had been prescribed morphine previously, that was an "aha" moment for Dr. Brajer. Michael stated that the morphine was helpful, and allowed him to get through the night. Michael had not been prescribed morphine for "some time". Michael did not inform Dr. Brajer of his opioid addiction. Dr. Brajer does not recall whether GNS requested prior medical records from any source. Michael asks that he be switched to morphine because it "worked" for him. At the time he had still not yet reviewed Dr. Steven Grossinger's charting for Michael, nor the Silberman report. He took the history from Michael.

At SX 1 at Tab D at 49, Dr. Brajer noted his reason for the medication adjustment in May 2014. When Michael stated that morphine had helped previously, he did not identify the prescriber. Michael stated that it was "several years" before. Hence, Dr. Brajer testified that a query to the PMP would not have been helpful. Dr. Brajer had no reason to question Michael's veracity. He passed the narcotics "sniff" tests.

Dr. Brajer added that BNS did not know if Michael had been using heroin while treating with GNS. They knew he had used the illicit drug in December 2014. Since there were no earlier tox screens, GNS did not know if he were using other illegal drugs. He added that a "savvy" user can "get around" screens. Screens are helpful. However, in 2014 screening was "not required". GNS now performs screens at least annually on patients, if not more often.

SX 1 at Tab D at 65 is Dr. Brajer's office note of July 30, 2014. That was Michael's next appointment. Michael's medications had been continued without office visits. A June 2014 visit was canceled on account of a lack of insurance coverage. When an insurer denied coverage for an injection or injections, Dr. Brajer continued to schedule office visits with him.

Michael's chart states that on July 9, 2014 Michael was informed that he "must keep the next appointment." Dr. Brajer was not aware why that note was written. He would not have seen that note at the time. Dr. Brajer accessed a "log sheet" displayed on a large board during the hearing. He wanted to view that sheet to "see what's going on". He also wanted to verify the reason and the correct anatomical area for the next injection. Michael canceled the injection visit due to insurance coverage problems.

He agreed that in July 2014 no one at GNS had seen Michael, but that his medications were refilled. In July the plan was to increase his morphine dosing to 30mg. Dr. Brajer admitted that Michael's current medications in July 2014 were incorrectly listed. *Id.* His daily morphine dosing was increased from 15mg to 30mg. Dr. Brajer again testified that while treating Michael he had not run a PMP report. July 14, 2014 was Dr. Brajer's last treatment of Michael.

Dr. Brajer was then asked questions about his curriculum vitae. He earned his baccalaureate at Johns Hopkins, and his medical degree at Hahneman. He completed a residency in anesthesiology, and a

fellowship in cardiology. He then practiced at Thomas Jefferson Hospital. He served as Chair at Germantown Hospital for four months. He began specialization in pain management at Northeast Hospital. He chaired a department at Montgomery Hospital and practiced there for 15 years. He founded the Montgomery Pain Center, where he practiced for ten years. He then joined the Grossingers in pain management practice in July 2008. Dr. Brajer is a diplomate in the American Academy of Pain Management. He is a member of the largest organization of pain management physicians.

Dr. Brajer testified that even if he had known the information in the Silberman report and in Dr. Steven Grossinger's charting for Michael, he would have treated Michael as he did. However, he would have engaged in a "more in-depth talk" with Michael.

In April 2014 Dr. Brajer performed a cervical epidural injection on Michael. He then described the injection procedure in some detail, including the guiding of the injection with the aid of fluoroscopy. He noted that the epidural was "smaller" than that employed during labor and delivery. The procedure requires care, with injection in the bony spinal canal. He described it by way of an analogy to a Bloody Mary cocktail, with reference to the celery stalk, the liquid surrounding it, and then inner and outer glass.

On April 9, 2014, Dr. Brajer had performed a third injection on Michael. The two discussed the discontinuation of Tramadol, which had been prescribed for one month, and substituting a low dose of Hydrocodone.

By May 28, 2014 the epidurals had been completed. In Dr. Brajer's practice usually three injections is the maximum amount, though there is hope that fewer can be performed. Michael's MRI disclosed a spondylosis or arthritic condition. He again provided a lengthy and technical explanation of the epidural procedure, with emphasis on the locations of injections and the type of medication employed. On May 28 Dr. Brajer decided to address radicular problems in the future, with a review of all procedures performed to date.

On May 28 Dr. Brajer made his third adjustment in Michael's medications. GNS treatment had gone from no medications for him, to the prescription of controlled and uncontrolled substances, and then adjustments in dosing. He reiterated that he changed Michael's medication to morphine because Michael

indicated the drug had been helpful in the past. Dr. Brajer noted that morphine is the least addictive of narcotic medications. Michael was maintained on two narcotic dosings per day. That schedule was to continue, though there was a medication change to morphine. He also reiterated that, looking back, he would not have altered the care which he provided for Michael.

Dr. Bruce Grossinger was then called. He identified a letter from himself to Anthony Kemmerlin, Sr., a Division of Professional Regulation investigator, dated January 7, 2015. The letter was admitted as SX 2. In the letter Dr. Bruce Grossinger states that he had "never seen or treated (Michael) in any way, and that the only connection to myself and the patient is that some of the computerized prescriptions utilize the names of myself and the other two doctors." SX 1 at 2. In his testimony Dr. Grossinger confirmed that he had never seen Michael. He prescribed medications for Michael on July 9, September 11 and November 3, 2014. He stated that he did sign off on certain refills, and that if documents show otherwise that was a "computer error".

Dr. Grossinger testified that he prescribed for Michael low doses of Hydrocodone and morphine. He did not change the scripts of other GNS physicians. He does not recall reviewing records on Michael. He acknowledged that he did have access to EMR's and to PMP reports. He knew that Dr. Brajer had performed injections based on abnormal MRI's and EMG's. He does not recall reviewing the Silberman report. He may have reviewed documents created by others on the office T-drive. He stated that he has discharged more patients from the GNS practice than the other physicians.

Dr. Bruce Grossinger testified that he acted based on information from his partners and GNS staff. To him the case seemed "routine". He bridged certain 30-day prescription cycles. He did review Dr. Steven Grossinger's notes of January 2014. He then admitted that he had reviewed Dr. Silberman's report. He deemed electronic communications "critical". He does not recall reviewing PMP reports concerning Michael. He "may have" done so. He then stated that he "probably did", though he did not note that fact in Michael's chart.

Dr. Grossinger testified that it is important to remain current with regard to Bd. Reg. 18.0. He added that new GNS consent forms discuss risks and benefits of pain medications. Dr. Grossinger stated

that he is "passionate" about helping patients. He did note Michael's signed consent regarding picking up a script. RX 3 at 46. The exhibit lists Michael's medications in July 2014 (MS Contin 15mg and Hydrocodone 5mg). The document also warns Michael about increasing his use of the medications over that prescribed. Dr. Grossinger did not make a separate note in Michael's chart on July 9, 2014. Typically that is not GNS protocol if a physician did not see a patient on a particular date. He just refilled the medications and provided the form to Michael.

Dr. Bruce Grossinger stated that he had access to Dr. Silberman's notes. During his testimony Dr. Grossinger stated that he was "nervous". He added that his "obsessiveness" serves him well in his practice. He usually does check Dr. Silberman's reports. He stated that he believes he did so in this case. He added that he was not aware of Michael's admitted daily heroin use. He further added that Dr. Lifrak should have stated "heroin addiction" in his records regarding Michael.

Dr. Grossinger stated that GNS knew that Michael had treated with Dr. Cary and then with Dr. Lifrak before presenting at GNS. He conceded that Dr. Silberman "possibly" knew of Michael's heroin use. Dr. Silberman would not "do some things". He is an "old guy, Vietnam veteran". Dr. Grossinger admitted that Dr. Silberman did not mention Michael's heroin use in his report. Dr. Silberman's January 29, 2014 report (RX 3 at 1) does not mention Michael's recent non-compliance, nor the reasons why he was no longer treating with Dr. Lifrak.

Dr. Bruce Grossinger testified that Clonodine can help patients with opioid dependence. GNS trusts Dr. Silberman's reports. Dr. Silberman did not mention Michael's Suboxone treatment with Dr. Lifrak. *Id.* In Dr. Grossinger's view, Dr. Silberman implied that Michael was still being treated with Suboxone. Dr. Grossinger stated that he thinks that he "would have" asked Michael about opioid dependence. Dr. Grossinger did not discuss Michael's care with Dr. Lifrak.

Mr. Liguori then cross-examined Dr. Grossinger briefly. Dr. Grossinger stated that the consent form signed by patients at the times when they pick up prescriptions is "redundant". It is not used every time for regular patients.

The State then called Mr. Kemmerlin, who testified without objection by telephone. He is a licensing investigator employed in the Division. In conjunction with this matter, he interviewed Dr. Lifrak. He also arranged for Dr. Lifrak's chart on Michael to be subpoenaed. Dr. Lifrak informed him that Michael had been discharged from his practice because of a failed toxicology screen and violation of his treatment agreement. Dr. Lifrak also stated that GNS should have contacted him because of Michael's long history of drug abuse and addiction.

Mr. Liguori then cross-examined Mr. Kemmerlin. Mr. Kemmerlin was not aware of the association between Dr. Silberman and Dr. Lifrak. Mr. Kemmerlin was aware that Dr. Silberman is providing assessments for GNS. At this point the State rested.

The attorneys then addressed certain evidentiary issues. Mr. Liguori renewed his objection to the admission of Mr. Balick's letter to Mr. Kemmerlin dated May 22, 2015 and found at Tab C of SX 1. Ms. Stewart argued that the letter was not sent to Mr. Kemmerlin as a "settlement offer". It was addressed to Mr. Kemmerlin and not to a Deputy Attorney General. It was a response to the CSR complaints filed against the three GNS physicians. Mr. Balick had copied the letter to GNS, and no subsequent amendments were made to it. In response, Mr. Liguori stated that a "response" is not a formal "answer" to a complaint. Since it was addressed to Mr. Kemmerlin, it was "less formal". The letter was addressed to the "hysteria" reflected in the State's complaints.

I admitted the exhibit. It was determined that the letter was in fact a response to the CSR complaints. It was mailed to Mr. Kemmerlin on behalf of GNS. It was not amended by Mr. Balick nor by GNS after the practice had received a copy of it. It was mailed to Mr. Kemmerlin at a time when Mr. Balick represented GNS and its physicians in related matters, and at a time when Mr. Balick had implicit or explicit authority to provide it to the investigator.

At the outset of the hearing Mr. Liguori, on behalf of the respondents, had offered the "complete" chart of Michael as maintained at GNS. A decision on the admission of that 158-page exhibit was deferred. Mr. Liguori argued that the document should be admitted because it provides a "full, fair record". Ms. Stewart has had an opportunity to review its contents, and to examine its authors regarding

its contents. He noted that some pages which may appear "new" are simply the reverse sides of documents already produced to the State. The 158-page exhibit formerly identified as RX A for identification was then admitted by this hearing officer as RX 3. At the request of the State, the copy of Bd. Reg. 18.0 was removed from the exhibit as that regulation was not a part of Michael's chart.

Finally, a printed copy of a "board" displayed electronically during the hearing was admitted as RX 4. That "board" provides a summary of the "encounters" with Michael at GNS between January 29, 2014 and December 8, 2014.

Mr. Liguori then stated that Dr. Steven Grossinger, Dr. Bruce Grossinger and Dr. Brajer did not have further testimony or additional documents to place into evidence. Mr. Liguori asked that counsel be permitted to submit their closing arguments to the hearing officer in writing after the hearing had adjourned. On behalf of the State, Ms. Stewart objected to written submissions and stated that she was prepared to close orally at that time. It was decided that written closing arguments would be permitted, with the proviso that the parties would not be permitted to submit new evidence via their closings. A schedule was established whereby the State would submit its closing, followed by the respondents' closing, and then a final rebuttal or reply by the State. Those arguments have now be submitted. They will be summarized in the "legal conclusions" portion of this recommendation, and will be made a part of the record in this case.

Findings of Fact

The notice of this hearing provided Dr. Bruce Grossinger and his counsel with the date, time, place and subject matter of these proceedings. The notice was in fact received by Dr. Grossinger's attorney, and both he and counsel attended the entirety of the hearing.

The following facts have been proven in the record of this case by a preponderance of the evidence. The initial facts provide important background information with concerning Michael prior to his presentation at GNS in late January 2014. Patient Michael was born in November 1972. During the period 2008-2011 Michael was involved in at least two and perhaps three or more motor vehicle accidents. The 2008 accident resulted in objectively discernable injuries to, *inter alia*, the neck and

shoulder and right arm. The 2011 accident aggravated the pre-existing injuries and further injured the left side. In 2014 Michael also experienced numbness in three digits of the left hand, cervical paravertebral tenderness and muscle spasm. An MRI disclosed straightening of the cervical lordosis. EMG and nerve conduction studies disclosed right C6-7 and left C7 radiculopathy. SX 1 at Tab D at 3.

According to a report prepared by Dr. Steven Grossinger for Michael's legal counsel and dated July 11, 2014, Michael initially treated with Dr. Ross Ufberg following the 2008 accident. SX 1 at Tab D at 61. Treatment by Dr. Ufberg continued after a 2010 accident. Dr. Ufberg prescribed Lyrica and Oxycodone.

A note in Dr. Ufberg's records and restated by Dr. Steven Grossinger in his July 2014 medical opinion letter to counsel indicates that Dr. Ufberg discharged Michael in March 2011 "due to inconsistencies in his urine drug screen." *Id.* at 62. (The record is unclear as to when and why Dr. Ufberg's records were provided to GNS. In the absence of evidence to the contrary, I will assume that the Ufberg chart was provided to Dr. Steven Grossinger by Michael's counsel so that he could address questions posed by that attorney in conjunction with personal injury claims made on his behalf. RX 3 at 59. At least with respect to Michael's care, it was not the practice of GNS in 2014 to request copies of medical records maintained by other physicians with whom Michael had treated prior to January 2014. That said, as of June or July 2014, at least, Dr. Steven Grossinger had access to all or portions of the chart maintained by Dr. Ufberg and the information contained therein. The medical opinion letter to counsel was produced to the State as part of Michael's GNS chart. There is no evidence that new medical documentation on Michael from the attorney was shared by Dr. Steven Grossinger with his colleagues.)

In or about March 2011, Michael became a patient of Dr. Damon Cary. Dr. Steven Grossinger had apparently also been provided with all or a portion of Dr. Cary's chart on Michael. Dr. Cary refilled Michael's prescriptions for Roxycodone and MS Contin and referred him to physical therapy. *Id.* A note in Dr. Cary's chart on Michael indicated that in August 2011 Michael would be referred to GNS for epidural injections. Dr. Cary prescribed medications for Michael through July 2012. According to Dr. Steven Grossinger's opinion letter to legal counsel, Dr. Cary noted "improvement with full resolution of

(Michael's) thoracic sprain discomfort." *Id.* at 63. Dr. Cary also noted that ongoing neck and low back pain restricted Michael's activities of daily living.

Michael then began treating for a brief period with Dr. Irwin Lifrak. Dr. Lifrak's chart was subpoenaed by the State in conjunction with the investigation of the instant case. Dr. Lifrak's chart was not requested by any of the physicians practicing in 2014 at GNS. Nor did any of the GNS physicians contact Dr. Lifrak to discuss Michael's course of treatment. The Lifrak chart is found at SX 1 at Tab E. It appears from the Lifrak chart that Michael presented to him on or about December 11, 2013. That is the date when Michael signed a form captioned *Delaware DMMA Informed Consent Form for Opioid Dependence Treatment* (SX 1 at Tab E at 2) and a form on which Michael acknowledged that he would be administered "Buprenorphine/Naloxone and/or Naltrexone" for the "sole purpose of assisting in my detoxification from heroin, Percocet, oxycontin, or other opioids..." *Id.* at 4.

On the latter form Michael was required to disclose all substances consumed within the seven days prior to his presentation to Dr. Lifrak. The first substance disclosed by Michael on December 11 was "heroin – daily". The final acknowledgement by Michael was that Dr. Lifrak had advised that Michael engage in substance abuse counseling.

Immediately following the two forms in the Lifrak chart is Dr. Lifrak's chart note of December 11, 2013. *Id.* at 6-7. In his assessment of Michael, Dr. Lifrak notes, "(p)atient usually uses over a Bundle of Heroin per day and has been doing so for 6 years with some periods of sobriety. Most recent use was yesterday." Dr. Lifrak notes the ongoing prescribed use of Cymbalta. Most of his physical findings after examination appear to be within normal ranges.

Dr. Lifrak notes that he engaged in a "lengthy, detailed discussion" with Michael regarding "opoid (sic) addiction and the options for treatment." He then notes that Michael elected to be treated by "Suboxone detoxification, followed by Suboxone maintenance with support group follow-up". Dr. Lifrak prescribed "Suboxone 8/2mg tablets", i.e. 8mg Buprenorphine/2mg Naloxone. Michael was instructed "in the strongest terms" to bring the medication to Dr. Lifrak's office and to take the first dose under

medical supervision, followed by observation in Dr. Lifrak's office. Michael agreed to "follow-up drug screens". *Id.*

Michael was again seen by Dr. Lifrak on December 12, 2013 "for Detox from Heroin". His December 12 note of that visit is found at SX 1 at Tab E at 8-9. The note reflects that Michael's "last use" was yesterday, i.e. the date when Dr. Lifrak first saw him. Dr. Lifrak notes the onset of withdrawal symptoms, including gastrointestinal upset, muscle aches and headaches. *Id.* Physical exam of most systems was again within normal ranges. Dr. Lifrak administered the first Suboxone 8/2 tablet to Michael and rechecked him 20 minutes thereafter. Both at that point and after another 20 minute check Michael felt "better" and was "more relaxed". Dr. Lifrak's diagnosis after the second visit was "opoid (sic) addiction, abdominal pain, myalgia, cephalgia". Michael agreed to join a support group, and was given "Suboxone 4mg/day in divided dose 14 strips." *Id.*

At the time of Michael's first visit with Dr. Lifrak he provided bodily fluid samples for toxicology screening. The LabCorp report resulting from those samples and generated within 24 hours of the donations is found at SX 1 at Tab E at 10. Michael tested negative for hepatitis. The report states that insufficient urine had been provided by Michael, and that he was being provided "re-collection instructions".

The final document in the Lifrak chart is his note dated January 14, 2014. SX 1 at Tab E at 11. That note states that Michael had produced "Dirty Urine". Dr. Lifrak therefore advised Michael that "inpatient treatment" should be undertaken by him. During the January 14 visit Michael expressed concern for "emotional depression and anxiety". *Id.* Dr. Lifrak diagnosed opioid abuse, anxiety and depression. His "plan" entered on January 14 reads: "No Suboxone was prescribed in view of positive drug screen".

The Lifrak chart does not contain a second toxicology screen report disclosing "dirty urine". Nor does the chart contain documentation of Michael's discharge by Dr. Lifrak. Nonetheless, the unrefuted record in this case establishes by a preponderance of the evidence that after a tox screen had disclosed "dirty urine", Dr. Lifrak discharged Michael.

At some point after January 14 and on or before January 29, 2014, Michael presented at Grossinger Neuropain Specialists (GNS) on referral from Dr. Yezdani. GNS is a medical practice with offices in Pennsylvania and Stanton DE. The three principals in the practice are Dr. Bruce H. Grossinger, Dr. Steven D. Grossinger and Dr. Jason Brajer. The regular staff in the Stanton office (where Michael was treated) consists of the three physicians, two front-desk employees, and 2-3 Medical Assistants. Though his name appears on the GNS letter head, Dr. Allen Silberman is an "independent" psychologist who performs psychosocial studies and evaluates pain status with respect to certain GNS patients and provides reports of his findings to the GNS physicians.

The focus of GNS is pain management. Both Dr. Steven Grossinger and Dr. Bruce Grossinger are Board-certified in neurology and pain management. The practice engages in diagnosis, evaluation and treatment of pain. Evaluative tools such as EMB's, nerve conduction studies and others are performed. Patients are treated with pain medications, interventional pain management such as injections, and other modalities. Though queries were not documented in Michael's GNS chart, the practice has access to the Delaware Prescription Monitoring Program (PMP).

On January 29 two licensed professionals generated reports concerning Michael on behalf of GNS. Dr. Steven Grossinger prepared an evaluative report on Michael to Dr. Khaga Yezdani. SX 1 at Tab D at 3. In addition, on January 29 Dr. Allen Silberman, a psychologist, prepared a "Psychotherapy Initial Evaluation" for the information of the GNS practitioners. *Id.* at 11-12.

According to the unrefuted testimony of Dr. Steven Grossinger, Dr. Silberman is a psychologist who sees or saw some GNS patients in order to provide "psychosocial insight" and analyses of the pain status of patients and other information to the GNS physicians. His name appears on GNS letterhead. He was not a co-owner nor employee of GNS, but worked as an independent psychologist to whom GNS physicians referred certain patients. He maintained set hours in the GNS Stanton office. Perhaps significantly, prior to January 2014 Dr. Silberman had maintained hours in Dr. Lifrak's office, presumably performing similar functions for Lifrak. In his formal written medical opinion in this case,

Dr. Staats states that Dr. Silberman "had knowledge of (Michael) and his treatment in another practice that was overseen by a family practitioner, Dr. Irwin Lifrak".

In the "subjective" portion of his January 2014 psychotherapy evaluation of Michael, Dr. Silberman summarizes a portion of his accident and injury history and prolonged pain subsequent to the 2008 motor vehicle accident. The pain caused sleep problems, depression and anxiety. A November 2013 workup following a prolonged anxiety attack was negative for cardiac disorder. His family physician had prescribed Xanax. Dr. Silberman notes that on two separate occasions Michael had participated in two-week outpatient programs provided by Rockford Mental Health Center. *Id.*

Dr. Silberman's evaluation contains the following statement: "It should be noted that (Michael) also suffers an opiate addiction that started five years ago as the result of Oxycodone and Morphine prescriptions from his physician." He adds that, as of January 29, 2014, Michael was "currently" being prescribed Clonidine and Zoloft by Dr. Lifrak, "who also manages his Suboxone which is used for opiate dependence." *Id.*

In the "objective" portion of the evaluation, Dr. Silberman notes that Michael had presented on or about January 29, 2014 with "flat affect and depressed and anxious mood" and "ongoing agitation". Dr. Silberman diagnosed no cognitive or perceptual disorder, and noted adequate insight into "himself and his overall situation". Dr. Silberman's final observation is that Michael's "proneness toward anxiety is likely to cause ongoing difficulties for him that can result in over somatization of his existing physical disorder". Dr. Silberman recommends a "plan" of continued psychotherapy and encouragement as to "his drug treatment program". Dr. Silberman also recommends treatment for Michael's ongoing chronic pain. *Id.* at 12. Though Dr. Silberman notes that Michael "will be seen again in approximately two weeks", the GNS chart does not reflect any subsequent psychotherapeutic evaluations by nor visits with Dr. Silberman in the following 10+ months of GNS care. I find that Dr. Silberman's psychotherapy evaluation was not performed gratuitously or to "paper" the GNS file. Rather, I find that it was requested by GNS and was prepared to inform the care of Michael by all GNS physicians, including Dr. Brajer.

In his testimony Dr. Steven Grossinger testified that Dr. Silberman saw GNS patients and evaluated them at the request of GNS physicians. He provides "psychosocial insight" regarding those patients. Dr. Grossinger testified that he was aware of the opiate addiction disclosed in the Silberman report at least by the time of Michael's second visit to GNS (in February 2014).

Michael's physical care and pain management began with Dr. Steven Grossinger's evaluation as recorded in his report to Dr. Khaga Yezdani dated January 29, 2014. SX 1 at Tab D at 3-4. Dr. Yezdani is apparently the physician who referred Michael to GNS. Dr. Steven Grossinger evaluated Michael on that date. He notes some symptom improvement after Michael's 2008 motor vehicle accident, with exacerbation resulting from the 2011 accident. He further notes that while Michael had treated with Dr. Cary, he had not received pain treatment during the prior year. *Id.* at 3. Dr. Steven Grossinger diagnosed greater cervical paravertebral tenderness and spasm on the right side as opposed to the left. A 2010 MRI disclosed straightening of the cervical lordosis with disc osteophyte at C3-4 and uncinated process hypertrophy on the left side at C5-6 and C6-7. *Id.*

EMG and nerve conduction studies were performed. They revealed evidence of right C6-7 and left C7 radiculopathy. Dr. Steven Grossinger notes that Michael was "not looking to have medications prescribed." Michael told Dr. Grossinger that he did not like Suboxone. Dr. Grossinger had apparently reviewed a "PRP" (sic) which disclosed that Michael "had gotten Suboxone last month though it was not refilled." Dr. Steven Grossinger proposes a course of "cervical epidural injection and consideration of this other cervical spine injection." *Id.* at 4.

On the date of his initial presentation to GNS, Michael signed a form "Pain Management Agreement." Both pages of the form are found at RX 3 at 57-58. Among other things, in the agreement Michael acknowledged that breach of its terms would result in his discharge as a GNS patient. Michael agreed not to attempt to secure controlled substances from any other practice without the knowledge of GNS. He agreed to use only one pharmacy in refilling his prescriptions. He agreed that he will comply with "any random drug test" that a GNS physician deems necessary. Failure to comply with such

requests may result in discharge. He agreed to use his medications as prescribed. Medications will not be refilled on an accelerated basis. *Id.*

Michael signed another, slightly different "Pain Management Agreement" on June 13, 2014. RX 3 at 63-64. (That is not a date recorded on RX 4 as the date of an "encounter" for Michael.) This second agreement was cosigned by Dr. Bruce Grossinger. Among other things, in this second agreement Michael again promises not to use any illicit drugs. He again promises to cooperate with any requests for blood or urine testing, to consume prescribed medications at their prescribed rate, and to bring unused pain medications "to every office visit". *Id.*

The course of treatment by GNS physicians commenced with a second visit by Michael on February 26, 2014 and continued until Michael's discharge by GNS on December 15, 2014. The course of treatment is summarized in RX 4.

The course of GNS care for Michael after January 2014 consisted of seven direct encounters and seven other occasions on which his prescriptions were refilled by GNS physicians. A brief summary of those encounters or refills is provided here for the information of the Board:

February 26, 2014:	Dr. Steven Grossinger performs second EMG test; Dr. Brajer performs cervical epidural injection
March 19, 2014:	Dr. Brajer performs second cervical epidural steroidal injection; due to acute low back pain, Meloxicam, Tizandine and Tramadol prescribed
April 9, 2014:	Dr. Brajer performs third cervical epidural steroidal injection; Tramadol discontinued; Hydrocodone 5/325mg prescribed
April 17, 2014:	Meloxicam and Tizandine refilled
April 30, 2014:	Dr. Brajer performs first cervical selective nerve root injection; low back issues "worsening"
May 8, 2014:	Hydrocodone 5/325mg refilled
May 28, 2014:	Dr. Brajer performs first cervical facet injection; Dr. Brajer prescribes Morphine Sulfate 15mg at nighttime; Hydrocodone dosing reduced from twice to once daily; Esgic prescribed for headache

June 9, 2014:	Hydrocodone 5/325mg dosing adjusted; Morphine Sulfate 15mg added
June 18, 2014:	Appointment with Dr. Brajer canceled due to "lapse in insurance"; urine drug screen was to be performed but sample could not be collected
July 9, 2014:	Hydrocodone 5/325mg and Morphine Sulfate 15mg refilled by Dr. Bruce Grossinger
July 30, 2014:	Follow-up visit scheduled with Dr. Brajer; injection canceled because coverage denied by insurance carrier; Dr. Brajer increases Hydrocodone dosing to twice daily and Morphine Sulfate 15mg to once every 12 hours
September 3, 2014:	Michael cancels appointment due to illness
September 11, 2014:	Hydrocodone 5/325mg and Morphine Sulfate scripts refilled by Dr. Bruce Grossinger
October 10, 2014:	Hydrocodone 5/325mg and Morphine Sulfate 15mg scripts refilled by Dr. Steven Grossinger
October 27, 2014:	Appointment with Dr. Brajer canceled by Michael
November 12, 2014:	Dr. Bruce Grossinger refills scripts for Hydrocodone 5/325mg and Morphine Sulfate 15mg; Dr. Grossinger notes that Michael must make and keep next appointment to receive further refill scripts
December 8, 2014:	Michael seen by Dr. Steven Grossinger; urine sample provided for screening; medications refilled
December 15, 2014:	Michael discharged after receipt of UDS results

Dr. Jason Brajer is an active licensee of the Board. He is a Diplomate of the American Board of Anesthesiology with subspecialties in Cardiac Anesthesia and Obstetrical Anesthesia. More details about his curriculum vitae are summarized above. He is also a Diplomate of the American Academy of Pain Management. He is a partner or co-owner of a joint pain management practice with Dr. Bruce Grossinger and Dr. Steven Grossinger. The practice, Grossinger Neuropain Specialists, has offices in Wilmington DE and Ridley Park PA. All of the care provided by Dr. Brajer for Michael was offered at the Wilmington office.

With respect to GNS care for Michael, Dr. Brajer was primarily the interventionalist. On February 26, 2014, he performed a cervical epidural steroidal injection at C7-T1 after a diagnosis of cervical radiculopathy and cervical spondylosis. RX 3 at 8. On that date Dr. Brajer planned a further injection three weeks hence. While Dr. Brajer's procedure note for the February 26 injection states that he had discussed the "risks and benefits" with Michael pre-surgery when securing his informed consent, I have found previously that it is more likely so that not so that the "risks and benefits" discussion pertained to the injection procedure and not the use of controlled substances. (As of February 2014 the GNS physicians had not yet begun to prescribe opioids for Michael.) The fluoroscopically guided procedure apparently occurred without complication.

On February 26 Michael also provided information for an "injection intake information" form. A category of information on the form is "Pain Medications/Other Medications". The entry after those subjects is "See List". Dr. Brajer testified that he wants the staff member taking the information to list the medications. He added that "now they do". No "list" was found in the GNS chart. Dr. Brajer stated that if one had been prepared, it would have been "shredded". He further added that no list was prepared or shredded because at the time GNS was not prescribing for Michael.

Prior to his first encounter with Michael, Dr. Brajer testified that he had not reviewed any pertinent PMP report. He had not reviewed Dr. Silberman's January 29 psychotherapy evaluation. He was not aware that Michael was undergoing Suboxone treatment.

Dr. Brajer's second cervical epidural steroidal injection was performed on March 19, 2014. RX 3 at 11. According to Dr. Brajer's note on that date, the first injection provided "moderate" relief and Michael desired to continue such treatment. Michael reported that he had recently "pulled his back". Dr. Brajer again examined Michael. Noting that GNS physicians had not prescribed for Michael before, Dr. Brajer determined to prescribe Meloxicam 15mg, ½ tab p.o. b.i.d., Tizanidine 4mg p.o. for spasm, and Tramadol 50mg p.o. b.i.d. p.r.n. *Id.* Dr. Brajer determined that a third and final epidural would be performed three weeks hence, and that lumbar injections would also be ordered.

Prior to the March 19 procedure, Dr. Brajer again discussed its "risks and benefits" with Michael. Michael's chart contains a number of informed consent forms jointly signed by Dr. Brajer and Michael before each procedure. The form signed by the two on March 19, 2014 is found at RX 3 at 53. The form provides a brief description of the planned procedure as well as certain "risks and benefits" flowing from it. The form also lists a number of alternative modalities to intervention: oral medication, physical therapy, biofeedback, spine mobilization and acupuncture. *Id.* Michael acknowledges that his questions had been answered. Dr. Brajer's March 19 note describes the conduct of the procedure in detail, and a radiological report is attached. *Id.* at 13. In March he did not review Dr. Steven Grossinger's records on Michael. He testified that GNS only maintains records in the Delaware office of the most recent encounter with a patient.

Michael's third cervical epidural was performed by Dr. Brajer on April 9, 2014. RX 3 at 14. The note on that procedure indicates that the second procedure provide less relief than did the first. Dr. Brajer notes that benefits from the epidurals had been "less than anticipated." Hence, Dr. Brajer determined that he would continue to focus on the cervical region by scheduling a selective nerve root block while postponing lumbar intervention. Dr. Brajer and Michael signed another consent form. Another radiological report regarding fluoroscopic guidance was attached. RX 3 at 16. Also on April 9, 2014, Dr. Brajer prescribed Hydrocodone 5/325 60 tabs for 30 days. SX 1 at Tab H. Though Dr. Brajer testified that it is his routine to have a "thorough talk" with patients about the "slippery slope" before prescribing controlled substances, he did not document such discussions. If the Board is consistent in applying the adage that "if it's not in the chart, it didn't happen", it is more likely so than not so that Dr. Brajer did not have the risks and benefits "talk" with Michael on any consistent or significant basis.

Three weeks later on April 30, 2014 Dr. Brajer performed cervical selective nerve root blocks at right C7 and C8. RX 3 at 17. Michael was examined in somewhat greater detail. Michael reported significant improvement regarding radiculopathy. Dr. Brajer's procedure note states that, accordingly, cervical facet blocks will be planned for the future. Michael complained of bilateral low back pain radiating to the right lower extremity. *Id.* Dr. Brajer diagnosed lumbar and cervical radiculopathy and

cervical spondylosis. His plan on April 30 was to perform the selective nerve root block and to order a lower MRI. Pending Michael's response after the April 30 procedure, a determination would be made whether epidurals or SI joint injections would be performed. After the procedure was described to Michael, he signed a consent form. The procedure was done with fluoroscopic guidance, and a radiological report was dictated and attached.

On May 8, 2014 Dr. Brajer refilled Michael's Hydrocodone script. According to the GNS chart, another cervical facet joint block bilaterally at C5-6, C6-7 and C7-T1 #1 was performed on May 28, 2014. RX 3 at 21. In his procedure note of that date Dr. Brajer notes that while relief had originally been provided in regard to the radiculopathy, the radicular pain had returned. He further notes that the April nerve root blocks had provided only "minimal benefit". In the May 18 note Dr. Brajer also states as follows: "We are going to adjust Mike's medications somewhat. In the past he was on morphine which seemed to help with his evening pain, as such, this will be added for this. The hydrocodone will be decreased to 5mg once a day in the morning." *Id.* He labeled Michael's reference to relief from morphine as an "Aha!" moment in his treatment. He further planned to have Michael return in three weeks for repeat lumbar selective nerve root blocks.

The May 28 note again involved a discussion of risks and benefits (of the procedure) and involved Michael signing a further consent form. The procedure is described in some detail, and is again accompanied by a radiological report. RX 3 at 23. On June 9, 2014 Dr. Brajer refilled Michael's Hydrocodone script, and wrote a new script for Morphine Sulfate ER 15mg, 30 tabs for 30 days.

Michael attended an office visit with Dr. Brajer on July 30, 2014. RX 3 at 31. He reviews Michael's care and notes that Delaware Physicians had denied injections in June and July, causing his interventional care to "start over from scratch." Dr. Brajer describes bilateral radicular pain, sharp and stabbing neck pain with radiculopathy, and lumbar radiculopathy. Dr. Brajer reiterates his intention to treat the neck pain before beginning back treatments. He examined Michael in some detail and noted modest lumbar range of motion. His impression was cervical radiculopathy, cervical facet dysfunction, spondylosis, and lumbar radiculopathy and facet dysfunction. He expresses a hope to get the situation

corrected with Delaware Physicians so cervical and lumbar treatments may continue. He determines to "increase his MS Contin from 15mg to 30mg and he will continue with the hydrocodone." *Id.* He observes that both medications will be increased from once daily to b.i.d "so we will be doubling both of these meds allowing them b.i.d. which is the standard dosage." The July 30 chart note is the last written by Dr. Brajer.

On August 7, 2014 Dr. Brajer refilled Michael's Hydrocodone script. According to a PMP report, that was his last prescription for Michael. On occasion when Michael went to GNS to pick up refill scripts, he was asked to sign a form such as is found at RX 3 at 44. The form listed the medications prescribed, instructed him to consume them on the prescribed schedule, and asked that Michael reaffirm his intention to abide by his pain management agreement. He verified that he understood this "informed consent for prescription pick-up". *Id.*

Dr. Brajer testified that he had no knowledge about Michael's heroin use, nor of the reason for his Suboxone treatment by Dr. Lifrak. He was unaware of Michael's opioid "dependence" or "addiction". When it was pointed out that Michael had admitted daily use of heroin to Dr. Lifrak and was treating with Suboxone, he stated that the Suboxone could have been prescribed to treat pain. He admitted that there was no reference to pain treatments in the Lifrak chart. SX 1 at Tab E. He conceded that the reference to "Suboxone detoxification" and other information in the Lifrak chart indicated Michael was treating for addiction.

Dr. Brajer did not ask Michael about the use of illicit drugs. He noted that "patients lie". Later in his testimony he testified that Michael "passed the sniff test" and he had no reason to question his veracity. Nor did the intake documents filled out by Michael on presentation at GNS or afterwards request information about illegal drug use. Nor do those forms contain a written discussion of "risks and benefits" of treatment with controlled substances. He agreed in his testimony that Michael was a patient at "high risk" for drug abuse. He also conceded that he would have learned more about Michael had he read Dr. Silberman's evaluation.

Dr. Brajer testified that GNS physicians had no reason to know if Michael was using heroin while treating there, nor other illicit drugs. He was equivocal on tox screening. While "savvy" users can get around them, they can be helpful. Dr. Brajer testified that in 2014 ordering UDS testing was not a requirement of pain management physicians. He testified that even if he had been aware of the information in Dr. Silberman and Dr. Steven Grossinger's earlier reports, he would have treated Michael as he did, while having more "in-depth" talks with him.

As an additional finding of fact in this case, I concur with the opinion of Dr. Staats on behalf of the three GNS physicians that there is "no evidence that the care offered by the physicians at Grossinger Neuropain Specialists caused or contributed to (Michael's) overdose with an illicit street drug." RX 2 at 15. The State did not argue that there was a proximately causative link, and did not produce expert testimony which would contradict Dr. Staats on the point.

Conclusions of Law

The notice of this hearing provided Dr. Brajer with the date, time, place and subject matter of the proceedings. The notice otherwise comported with legal requirements for notices of hearings before the Secretary and the Controlled Substance Advisory Committee. Dr. Brajer's counsel received the hearing notice, and both he and his attorney attended the entirety of the hearing.

Delaware law provides that the Secretary of State shall act as the registering authority for Controlled Substance Registrations (CSR's) in this State. The Secretary may issue CSR's to practitioners who have been issued active, underlying professional licenses and who intend to prescribe controlled substances included in Schedules I-V of the Delaware Uniform Controlled Substances Act (UCSA). CSR's may be issued by the Secretary of State unless he determines that the issuance of a CSR would be inconsistent with the public interest. In making a determination of the "public interest", the Secretary shall consider whether, *inter alia,* a practitioner (1) maintains effective controls against diversion of

controlled substances, (2) is in compliance with applicable federal, state and local laws, or (3) presents "any other factors relevant to the public interest". 16 *Del. C.* Sec. 4733.

Upon a sufficient factual showing after notice and a hearing which has provided procedural due process, the Secretary may suspend or revoke or otherwise discipline a CSR held by a practitioner upon a showing that continued registration would be inconsistent with the public interst. 16 *Del. C.* Sec. 4735. In assessing the "public interest" impact of conduct alleged against the holder of a CSR, the Secretary may consider those factors listed at Sec. 4735(b). In furtherance of his duties under the USCA, the Secretary may consult with the Controlled Substance Advisory Committee (CSAC) and may direct that the CSAC review and consider this recommendation before the Secretary takes final action in the matter. 16 *Del. C.* Sec. 4731(b). These are all valid means and ends rationally related to the legitimate State purpose of ensuring that the prescription of controlled substances is consistent with the public interest.

In its complaint against Dr. Brajer in Case No. 38-03-15, the State contends that Dr. Brajer has violated the UCSA in three respects. SX 1 at Tab A at 13. First, the State claims that Dr. Brajer has violated 16 *Del. C.* Sec. 4735(b)(1). That section of the Act provides for CSR discipline if a registrant "(h)as failed to maintain effective controls against diversion of controlled substances into other than legitimate medical, scientific or industrial channels." *Id.*

The State has filed a companion licensure case against Dr. Brajer. SX 1 at Tab A at 16. By agreement of the parties, that case was consolidated with this one for purposes of creating a single factual record. In its licensure case against Dr. Brajer (Case No. 10-122-15), the State made a similar allegation regarding "controls" which was based on language in Regulation 18.0 *et seq* adopted in 2012 by the Board of Medical Licensure and Discipline. Specifically, the State alleged in the licensure case that Dr. Brajer had violated Bd. Reg. 18.4 of the Board's rules on the *Use of Controlled Substances for the Treatment of Pain.*

That provision in Bd. Reg. 18.0 states that patients "at high risk for medication abuse" or who have a "history of substance abuse" must sign pain management agreements outlining certain conditions, including (a) urine/serum medication levels screening when requested, (b) number and frequency of prescription refills, (c) reasons for which drug therapy may be discontinued (including violations of such agreements), and (d) that patients receive prescriptions from only one licensed prescriber and fill them at only one pharmacy "where possible". It was generally agreed by the GNS physicians that Michael was a patient at "high risk" for medication abuse. Further, a psychotherapy evaluation performed when Michael first presented at GNS informed Dr. Brajer and his colleagues that Michael was an "addict" treating with an immediately prior provider with Suboxone.

In my companion recommendation to the Board of Medical Licensure and Discipline, I concluded as a matter of law that the State had proven a violation of Bd. Reg. 18.4 by Dr. Brajer. For the reasons stated in that recommendation, I find that Dr. Brajer has also violated 16 *Del. C.* Sec. 4735(b)(1). I adopt and incorporate those conclusions here. I note that the UCSA requires the imposition of "effective controls" on patients who are being prescribed controlled substances primarily in order to aid in the detection of "diversion" of drugs into non-legitimate "channels". The primary purposes of the use of controls with "high risk" patients under Regulation 18.0 are to detect diversion as well as to determine whether a patient is acting in compliance with his prescription regimen and whether he is using illicit drugs. Regardless of the reasons for the implementation of controls in pain management practice, both the UCSA and the Board of Medical Licensure and Discipline require them.

I will briefly summarize my conclusions regarding the allegation that Dr. Brajer failed to "maintain effective controls" with respect to Michael. In his initial and updated pain management agreements, Michael was clearly informed that he "will submit to a blood or urine test if requested". See, e.g. RX 3 at 132. Bd. Reg. 18.4 requires that the pain management physician secure such an agreement from a patient and also "use" the agreement to verify compliance.

In this case Michael was purportedly ordered to provide a urine sample for testing in June 2014, or at least five months after he began to treat with GNS. However, Michael canceled his June encounter ostensibly for reasons of a "lapse in insurance". RX 4. Dr. Brajer did not order Michael to appear at GNS to provide a sample at any time thereafter until a sample was finally provided in December 2014. The sample was positive for heroin and he died within days after providing it. In my opinion the failure to secure a sample from Michael at any time from January-June, and then from June-December, constituted a failure by Dr. Brajer (and his colleagues) to "use" the clear language in Michael's agreements and to insist on the performance of a UDS. Hence, I have concluded that Dr. Brajer violated Sec. 4735(b)(1) of the UCSA.

I note that the medical board has not mandated a specific number of UDS's per year, nor a schedule for their use, nor the types of events which should trigger a UDS. The request that a patient provide a bodily fluid sample is properly left to the discretion of the physician. However, in the context of this case, and with clear information in Michael's GNS chart that he was a heroin addict, Dr. Brajer failed to employ reasonable vigilance in securing a sample from Michael for almost a year.

The second iteration of Michael's pain management agreement required that he bring "unused pain medication to every office visit". Pill counts may be effective controls and means by which to determine if a patient has been compliant regarding prescribed medications, or has been diverting them . However, there is no evidence that any pill counts were performed during his 11 months' treating with GNS. Even though Dr. Brajer testified that Michael did not provide the outward appearance of a drug seeker, in my view that does not constitute a valid reason to choose to ignore the important verification provisions in Michael's pain management agreements for his entire period of care.

The State next contends that Dr. Brajer violated 16 *Del. C.* Sec. 4735(b)(2). That section of the UCSA provides for CSR discipline if a registrant "(h)as failed to comply with applicable federal, state or local law." *Id.* Finally, the State alleges that Dr. Brajer also violated 16 *Del. C.* Sec. 4735(b)(8). That

section provides for discipline if a registrant "(h)as engaged in any conduct the Secretary finds to be relevant and inconsistent with the public interest." *Id.* I will address those two sections in the same discussion.

While a patient of GNS in 2014, it is uncontroverted that Michael was treating for chronic and objectively diagnosed pain resulting from multiple motor vehicle accidents. Pain management is the primary focus of GNS. As such, Michael's care by that practice was clearly governed by Regulation 18.0 of the Board of Medical Licensure and Discipline. While the expert witness called by the GNS providers (Dr. Staats) was mistaken in assuming that Bd. Reg. 18.0 had not yet taken legal effect in 2014, there was no other effective argument made that the regulation did not apply to the prescription of controlled substances by GNS providers (including Dr. Brajer) for Michael. In my companion recommendation to the Board of Medical Licensure and Discipline on the State's professional licensure complaint against Dr. Brajer, I have dismissed the contention by the Medical Society of Delaware in its April 2013 *Journal* that Bd. Reg. 18.0 *et seq* is merely a "guideline" or an "educational tool" and does not establish pain management standards of care in this State.

Since Bd. Reg. 18.0 *et seq* is a regulation properly adopted within its subject matter authority by the Board of Medical Licensure and Discipline, the regulation has the force and effect of law in Delaware. The Board is obligated to adopt regulations consistent with the Medical Practice Act and which carry out its powers and duties under law. 24 *Del. C.* §1713(a)(12). The Board has the sole authority in this State to supervise, regulate and impose professional discipline upon physicians. 24 *Del. C.* §1710(a). Acting within its sole discretion, the Board has determined that it is "dishonorable or unethical conduct" under 24 *Del. C.* §1731(b)(3) for a registrant to fail to "comply with the Board's regulations governing the use of controlled substances for the treatment of pain." Bd. Reg. 8.1.12. To act contrary to Bd. Reg. 18.0 therefore constitutes the failure to comply with applicable state law as that term is used in 16 *Del. C.* Sec. 4735(b)(3).

In addition to the preceding legal conclusions, I further find that it would be a reasonable exercise of administrative discretion for the Secretary of State to conclude that actions by a registrant which violate Bd. Reg. 18.0 *et seq* are "inconsistent with the public interest" under 16 *Del. C.* Sec. 4735(b)(8). It is more likely so than not so that the prescription of controlled substances inconsistent with the provisions of Bd. Reg. 18.0 presents a risk to the public health, safety and welfare, and specially to the health of those members of the public who are treating for chronic, non-cancer pain. Indeed, the Board of Medical Licensure and Discipline has determined in its disciplinary matrix that failure to comply with Bd. Reg. 18.0 may result in discipline up to and including license revocation. Bd. Reg. 17.12.3. Based on these legal conclusions, I have determined that additional findings of violations of Bd. Reg. 18.0 by Dr. Brajer should also be considered in the "public interest" analysis under Sec. 4735(b)(8) of the UCSA.

In addition to the conclusions summarized above regarding Dr. Brajer's failure to "maintain effective controls", I have drawn additional legal conclusions in the licensure recommendation submitted previously which I will briefly summarize here.

First, I have concluded previously and I conclude here that Dr. Brajer had failed to obtain the prior treatment records of Dr. Lifrak or to otherwise communicate with Dr. Lifrak in violation of Bd. Reg. 18.1.1. This in light of the fact that a psychotherapy evaluation performed by Dr. Silberman at the request of GNS had identified Michael as opioid dependent and an "addict" treating with Dr. Lifrak with Suboxone. Though the Silberman evaluation was contained in Michael's GNS chart from the date of his initial presentation, Dr. Brajer conceded that he had not read it. As I have stated in the earlier recommendation, in my view the reasonable pain management physician would seek to apprise himself of the contents of the Silberman report, which was prepared at the request of and to inform Michael's treatment by GNS. According to a PMP report in this case, Dr. Brajer prescribed opioids for Michael on at least three occasions. SX 1 at Tab H. Bd. Reg. 18.1.1 requires that treating pain physicians gather medical histories on patients, with special emphasis on collecting pertinent history for known drug abuse or addiction.

The Silberman report provided clear and unmistakable evidence to Dr. Brajer that only through requesting the Lifrak chart or, at a minimum, speaking with Dr. Lifrak, could Dr. Brajer be adequately apprised of the nature and extent of Michael's drug addiction while he was prescribing opioids for treatment of his pain. Though Dr. Brajer claimed during the hearing that he would not have changed Michael's care plan had he known of the addiction, nonetheless he conceded that the knowledge would have caused him to have more extensive discussions on drug abuse with Michael. In my view the State has proven a violation of Bd. Reg. 18.1.1 by Dr. Brajer in that his charting of Michael's care contained a critically incomplete medical history.

In the companion recommendation I further concluded that Dr. Brajer had acted in violation of Bd. Reg. 18.3, which requires the discussion and documentation of the discussion with a patient of the risks and benefits of the use of controlled substances. Michael's chart does not reflect the documentation of any such discussion between Michael and Dr. Brajer. Though before each interventional procedure Michael signed a form acknowledging that a "risks and benefits" discussion was had with Dr. Brajer, I have found in the earlier recommendation that the form referred to the risks and benefits of the planned injection or nerve block, and did not refer to the more general subject of the use of controlled substances in the treatment of pain.

Since there is no documentation by Dr. Brajer that he engaged in the required "risks and benefits" discussion, I find that it is more likely so than not so that no such discussion was had. If such a discussion was had, it was apparently such a summary conversation that Dr. Brajer chose not to chart it. Dr. Brajer admitted that had he chosen to inform himself by reading the Silberman report and learning of Michael's addiction, he would have discussed the subject of drug abuse with him at length.

In its licensure case against Dr. Brajer, the State also alleged that he had failed to "keep accurate and complete records" regarding Michael in violation of Bd. Reg., 18.7 and failed to "adequately maintain and properly document patient records" in violation of Bd. Reg. 8.1.13. I concluded that both

allegations had been proven. Dr. Brajer's charting for Michael describes no discussions with him of the "risks and benefits". Even though he testified that he had not read it, Dr. Silberman's evaluation described Michael as an addict yet Dr. Lifrak's chart had not been requested. The Board has held in previous proceedings that the risk of harm to patients is enhanced when treating physicians fail to request records from providers who had previously prescribed controlled substances.

Due process has been afforded in these proceedings.

Recommendation

Based on the relevant evidence in this case and the findings of fact and conclusions of law set forth above, the following is recommended to the Secretary of State:

1. That the Secretary of State hold in abeyance any final action with respect to the Controlled Substance Registration currently issued to Dr. Jason Brajer until the Board of Medical Licensure and Discipline shall issue a final order in Case No. 10-122-15;
2. That if the Board shall agree with the recommendation of the undersigned hearing officer that the medical license held by Dr. Brajer should be placed on probation for a period of one year, or if the Board shall determine that such period of license probation should continue for such other period of time as the Board, in its sole discretion, deems appropriate, then it is recommended that the Controlled Substance Registration (CSR) held by Dr. Brajer be placed on probation for a like period;
3. That if the Board further agrees that such probationary period may only be terminated no sooner than six months after the issuance of the Board's final order in Case No. 10-122-15 upon a showing of full compliance by Dr. Brajer with all terms and conditions of the Board's order, or if the Board shall determine that such petition may be submitted by Dr. Brajer on some other schedule, that the Secretary not lift the probationary period for Dr. Brajer's CSR until and unless the Secretary is presented with such order by the Board terminating such probationary period;
4. That if the Board of Medical Licensure and Discipline shall suspend or revoke the medical license held by Dr. Brajer, a Board order so stating shall result in the suspension or revocation of Dr. Brajer's CSR accordingly and as a matter of law;
5. That pursuant to 16 *Del. C.* Sec. 4735(d), a civil fine be imposed upon Dr. Brajer in the amount of $3,000, payable within 30 days of the date of the final order of the Secretary, in the form of a draft made payable to the "State of Delaware";
6. That the final order of the Secretary be deemed public disciplinary action reportable to pertinent public practitioner data bases.

Roger A. Akin
Chief Hearing Office

Dated: July 26 , 2016